IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON,
Plaintiff,

v.

CIVIL ACTION NO. 3:17-01362

AMERISOURCEBERGEN DRUG CORPORATION, et al.,
Defendants.

CABELL COUNTY COMMISSION,
Plaintiff,

v.

CIVIL ACTION NO. 3:17-01665

AMERISOURCEBERGEN DRUG CORPORATION, et al.,
Defendants.

PLAINTIFFS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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Between May 3, 2021, and July 12, 2021, the Court conducted a bench trial in the above-captioned matter. Closing arguments were held on July 27 and July 28, 2021.

Plaintiffs the City of Huntington and Cabell County, a West Virginia city and a West Virginia county ("Plaintiffs" or "Cabell and Huntington"), proceeded in this case on a single cause of action against Defendants AmerisourceBergen Drug Corporation ("ABDC"), Cardinal Health, Inc. ("Cardinal"), and McKesson Corporation ("McKesson"), three prescription drug distribution companies (collectively "Defendants"). That cause of action was public nuisance, for which Plaintiffs sought relief in the form of abatement of the nuisance. The Defendants asserted multiple theories of defense under common law. Set forth herein are the Court's findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52.

FINDINGS OF FACT

Because this case was tried before the Court as a bench trial, the Court's findings are presumed to be based on admissible evidence. *Fishing Fleet, Inc. v. Trident Ins. Co., Ltd.,* 598 F.2d 925, 929 (5th Cir.1979); *see also Chicago Title Ins. Co. v. IMG Exeter Associates Ltd. P'ship,* 985 F.2d 553, 1993 WL 27392 at *4 (4th Cir.1993) (unpublished); *see also Harris v. Rivera,* 454 U.S. 339, 346 (1981) ("In bench trials, judges routinely hear inadmissible evidence that they are presumed to ignore when making decisions."). Accordingly, the Court finds it unnecessary to rule on each separate objection raised by the parties. The Court has considered those objections relating to the evidence supporting the findings contained herein and, to the extent such objections relate to evidence the Court cites in support of its findings, such objections are hereby overruled.

To the extent any evidence in the record conflicts with one of the facts found below, the Court has weighed the competing evidence and found that the greater weight of the evidence

weighs in favor of the facts as set forth. The Court, having heard testimony of the witnesses sworn and examined in open court, having observed their demeanor and credibility, having read sworn testimony by designation, having reviewed the exhibits admitted into evidence, and being fully advised in the premises, finds as follows:

I. There is an Opioid Epidemic in Cabell and Huntington.

1. The Court finds that there is an opioid epidemic in Cabell and Huntington, West Virginia, and that this epidemic constitutes an unreasonable, significant, long-lasting, and continuing interference with the public health, public safety, public peace, public comfort, and public convenience of the communities of Cabell and Huntington.

2. Prescription opioids are a "Schedule II" drug, pursuant to U.S. Drug Enforcement Administration regulation, which means that they have a recognized medical use, but they also have a high potential for addiction.[1]

3. At least 165,000 Americans died of opioid-related causes in the current epidemic between the years 2000 and 2014" to "Since 2000, well over 300,000 Americans have lost their lives to an opioid overdose."[2]

4. West Virginia likewise "has been experiencing a public health epidemic of drug overdose deaths for more than a decade."[3]

5. Former West Virginia Bureau of Public Health Commissioner, Dr. Rahul Gupta, described West Virginia as "ground zero" for the national opioid epidemic, the hardest-hit state in the country.[4]

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[1] 5/4/21 Trial Tr. (Waller) at 37.

[2] DEF-WV-01597 (Sept. 2019 OIG Rpt), 00002.

[3] P-41213_00003 (WV DHHR 2001-2015 Historical Overview).

[4] 5/5/21 Trial Tr. (Gupta) at 74, 77; 5/6/21 Trial Tr. (Gupta) at 96.

6. By 2016, West Virginia had the highest rate of opioid-related overdose deaths—43.4 deaths per 100,000 people—in the United States, with the majority of those deaths attributed to synthetic opioid medications, such as oxycodone and hydrocodone, and illicit synthetic opioids, such as heroin.[5]

7. As stated by Dr. Gupta, whenever any condition is causing West Virginians to die year after year by double percentage increases, that issue becomes a public health matter, as was the case with people using opioids, becoming addicted, and dying from overdosing on opioids.[6] The opioid epidemic has become such a public health crisis that the State of West Virginia Board of Medicine issued a statement declaring that the use of opioid analgesics poses a significant threat to the health and safety of individuals and public health.[7]

8. Cabell and Huntington are among the West Virginia communities hardest hit by the opioid epidemic.

9. According to United States Census Bureau figures, the population of Cabell and Huntington is 99,946.[8]

10. From 2001 to 2018, there were 1,151 overdose deaths in Cabell County, of which 1,002 (roughly 87% of the total) were opioid-related. From 2001 to 2017, the fatal overdose rate in Cabell County increased from 16.6 to 213.9 per 100,000.[9]

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[5] DEF-WV-01597 (Sept. 2019 OIG Rpt.).

[6] 5/5/21 Trial Tr. (Gupta) at 59-60.

[7] DEF-WV-01935.00004 (State of West Virginia Board of Medicine Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain).

[8] 5/11/21 Trial Tr. (McCann) at 125.

[9] 6/10/21 Trial Tr. (Smith) at 134-135, 139-40.

11. In 2015, Huntington's drug overdose death rate was 116 deaths per 100,000 population, the highest of any community in the nation. Cabell County's opioid overdose rate is higher than that of West Virginia, which itself is above the national average.[10]

12. From 2015 to 2020, Cabell County experienced 6,494 overdoses, a staggering and transformational number in a community of fewer than 100,000 people.[11] This means that the average number of overdoses per year during the past five years has been greater than one percent of the County's population.

13. Since 2010, approximately 2,500 newborns in Cabell County have been born with neonatal abstinence syndrome ("NAS").[12]

14. The opioid epidemic thus has had a devastating impact on public health and public safety.[13] As former Huntington Police Chief, Skip Holbrook, testified: "I saw my town being decimated by addiction."[14]

15. The costs of the opioid epidemic in Cabell and Huntington are enormous, running into the billions. Plaintiffs' health economics expert, Dr. Thomas McGuire, estimated the costs—including loss of human life from overdoses, morbidity from OUD and related disease, loss of

[10] 6/11/21 Trial Tr. (Keyes) at 201.

[11] 5/6/21 Trial Tr. (Priddy) at 197-198; P-44281 (Drug Overdose Statistics Cabell County Emergency Medical Services 2015); P-41060 (Cabell County EMS OD Call 2015-2018 Quarterly); MC-WV-02100 (Drug Overdose Statistics Cabell County EMS 2018-2020). EMS overdose calls peaked in 2017 with 1,831, and Connie Priddy noted that about 95 percent of EMS calls were opioid related. 5/6/21 Trial Tr. (Priddy) at 224-225; P-41060 (Cabell County EMS OD Call 2015-2018 Quarterly).

[12] 5/21/21 Trial Tr. (Werthammer) at 18.

[13] *See*: 5/12/21 Trial Tr. (Zimmerman) at 173; 5/21/21 Trial Tr. (Werthammer) at 19-20; 7/2 Trial Tr. (Gilligan) at 180.

[14] 6/17/21 Trial Tr. (Holbrook) at 220.

property values, and crime—to be $3.2 billion between 2006 and 2018.[15] Indeed, the costs estimated by Dr. McGuire are greater than the cost of Plaintiffs' Abatement Plan, which is roughly $2.5 billion.[16] Deaths from opioid overdoses not only mean lost lives, but also the loss of companionship, family, and parental support.[17]

16. The opioid epidemic has increased crime rates, decreased property values, and adversely affected neighborhoods throughout Cabell and Huntington.[18] The Huntington area has sustained high costs related to healthcare, criminal justice, and other public services due to the epidemic.[19] The burden of the opioid epidemic is borne by the community as a whole—including law enforcement, first responders, healthcare workers, the courts, employers, teachers, and families—and by local governments like Plaintiffs which are responsible for serving their citizens.[20] The epidemic implicates all parts of Huntington's budget.[21]

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[15] 6/17/21 Trial Tr. (McGuire) at 28-32. The Council of Economic Advisors has placed a value of a statistical life ("VSL") of $9.3 million dollars (in 2014 dollars) per life lost to the opioid epidemic. Dr. McGuire testified that the adjusted VSL for lives lost in Cabell and Huntington due to prescription opioids is $2.8 billion. The total excess healthcare costs for prescription-caused OUD in Cabell Huntington, 2006 to 2018, are $494 million. *Id.*

[16] 6/29/21 Trial Tr. (Barrett) at 106, 109.

[17] 6/16/21 Trial Tr. (Yingling) at 158, 162.

[18] 5/27/21 Trial Tr. (Zerkle) at 97 (opioid epidemic has turned the Community into a recovery center), 119-220 (addiction is draining Cabell County's workforce, reducing the population and tax base; Huntington owns 350-plus abandoned homes); 5/21/21 Trial Tr. (Lemley) at 119 (drug and property crime spiked in 2013-14).

[19] 6/11/21 Trial Tr. (Keyes) at 205 (opioid hospitalizations in West Virginia have increased since 2009); 5/27/21 Trial Tr. (Zerkle) at 98 (jail costs while Cabell was running deficits), 106-07 (Cabell has had to expand School Resource Officers from one to five; new 24-hour communication line from police to schools re kids with affected parents).

[20] 5/28/21 Trial Tr. (O'Connell) at 18, 27; 6/30/21 Trial Tr. (Williams) at 62.

[21] 6/30/21 Trial Tr. (Williams) at 142-143, 5/27/21 Trial Tr. (Zerkle) at 99-100.

17. The opioid epidemic has broadly affected the people of Cabell and Huntington. As stated by Huntington's City of Solutions report: "The opioid epidemic is a non-discriminating disease. It does not consider economic status, race, ethnicity, gender, religious affiliation, or political persuasion. It affects rural and metropolitan regions. It has attacked villages, towns, and cities. Huntington, West Virginia, has been drastically affected."[22] Fire Chief Jan Rader testified of the opioid epidemic that: "Nobody is immune from it" and "There's no boundaries here."[23]

18. In 2004, only a small area of Huntington had drug offenses, but by 2014, drug offenses had become prevalent throughout the city and by 2016 engulfed every neighborhood.[24] An MODCP investigation showed that by 2016, overdoses were occurring all over Huntington.[25]

19. In light of the foregoing, Defendants and their employees have conceded that an opioid epidemic exists in the United States and in Cabell and Huntington.[26]

20. The Court agrees and sets forth below its findings with respect to the many and interrelated public health and safety harms of the opioid epidemic in Cabell and Huntington.

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[22] DEF-WV-02653.00005 (The City of Solutions: Huntington, WV).

[23] 5/7/21 Trial Tr. (Rader) at 31-32; *see also* 5/6/21 Trial Tr. (Priddy) at 215 (There is no typical overdose victim, it cuts across every, gender, race, and socioeconomic line. Cabell County EMS has been called to overdoses scenes from apartments with dirt floors to multimillion-dollar homes.); 6/17/21 Trial Tr. 29 (Holbrook) at 198 (The opioid epidemic went from one end of the city to the other, affecting people from all walks of life. It didn't matter where you lived, what race you were, or how much money you had. People from all backgrounds became addicted to opioids and fueled the epidemic.), 224-25 (Every person in Huntington had some connection to the opioid epidemic.).

[24] 5/21/21 Trial Tr. (Lemley) at 173-174; P-41850_00010 – 2017 MODCP Strategic Plan (showing "heat maps" of spreading drug-offense crimes in Huntington).

[25] 5/21/21 Trial Tr. (Lemley) at 153.

[26] *See*, *e.g.*, 5/19/21 Trial Tr. (Perry) at 200; 5/12/21 Trial Tr. (Zimmerman) at 173; Hartle, 7/31/18 30(b)(6) Dep. at 365-66; Hartle, 8/1/18 Dep. at 35-36; Boggs, 1/17/19 Dep. at 34:19-35:7.

A. Prevalence of Prescription Opioids and Diversion in Cabell and Huntington

21. Between 2006 and 2014 alone, when opioid diversion and addiction already were widespread, *Defendants distributed 81,239,625 dosage units of oxycodone and hydrocodone* to retail pharmacies in Cabell and Huntington,[27] with combined population of fewer than 100,000 people.

22. Historically, the Appalachia region did not have much of an illicit opioid trade. Around the year 2000, however, it started to become an epicenter for prescription opioid diversion, abuse, and addiction.[28]

23. The opioid crisis during the first decade of this century was one primarily of prescription opioid addiction.[29]

24. By 2006, prescription opioids had become the most abused form of prescription drugs in the Appalachia region.[30]

25. By 2010, diversion and abuse of prescription drugs was an epidemic in the region, exacting a significant cost in life, health, property, and well-being from Appalachia communities.[31]

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[27] 5/10/21 Trial Tr. (McCann) at 92.

[28] *See* 6/10/21 Trial Tr. (Smith) at 216.

[29] P-41508_00030 (2002 AHIDTA Threat Assessment); 6/10/21 Trial Tr. (Smith) at 216; 6/28 Trial Tr. (Alexander) at 26-27.

[30] DEF-WV-00043.00002 (2006 AHIDTA Annual Report); *see also* 6/10/21 Trial Tr. (Smith) at 143-46 (describing Journal of American Medical Association 2008 study of overdose death certificates in West Virginia in 2006, finding that over 60% of the deaths were associated with prescription drug diversion).

[31] P-44068_00002, 00009 (2010 AHIDTA Annual Report).

26. In 2011, the Huntington Police Department identified the illegal diversion of powerful pain medications such as oxycodone and oxymorphone as the most prevalent emerging threat to the community.[32]

27. In 2011, the Huntington Police Department also seized large quantities of diverted prescription opioids, typically OxyContin, Opana, and Roxy 30s, while also seeing a noticeable increase in drug offenses.[33]

28. The Huntington Police Department found that people could obtain prescription opioids through various means, often starting with a doctor's visit, the development of dependency, and the emergence of an appetite for opioids that led people to obtain them by other means.[34]

29. By 2012, abuse of diverted prescription drugs was an epidemic in the City of Huntington, exacting tragic costs from the community, overburdening law enforcement, crowding the City's jails and treatment facilities, undermining the employability of the workforce, and devastating families, so that by 2014, the Huntington Police Department identified diversion and abuse of prescription drugs along with the pervasive drug culture and associated crime as the greatest threats to ever face the community.[35]

30. Trafficking and abuse of diverted prescription opioids were the driving forces behind public health harms and drug-related crime during the 2000s.[36]

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[32] P-41230_00019, 00021 (2011 HPD Annual Report).

[33] 5/21/21 Trial Tr. (Lemley) at 134-35, 148.

[34] 6/17/21 Trial Tr. (Holbrook) at 198-99.

[35] P-41374_0002 (2012 HPD Threat Assessment); P-41527_00001 (2014 HPD Threat Assessment).

[36] P-41510_00034 (2005 AHIDTA Threat Assessment).

31. During this time, law enforcement and first responders observed large numbers of people in possession of prescription opioids, pill bottles on the streets, and other evidence of widespread prescription opioid diversion and abuse in Cabell and Huntington's communities.[37]

32. The West Virginia Overdose Fatality Analysis, which examined death records for 881 individuals who died from an overdose in West Virginia during 2016, found that 81% of decedents had interacted with at least one health system before their death; 33% had tested positive for a controlled substance, but had no record of a prescription at the time of death, indicating diversion of a prescribed controlled substance; and that 91% of all decedents had a documented history within the State's Controlled Substances Monitoring Program.[38]

B. Prevalence of Opioid Use Disorder (OUD) in Cabell and Huntington

33. As of 2017, more than 10% of the population of Cabell County, the City of Huntington, and Wayne County were addicted to opioids.[39]

34. In 2018, the prevalence of OUD in Cabell and Huntington was *8.9%*, which represents approximately 8,252 people. Plaintiffs' epidemiology and OUD expert, Dr. Katherine Keyes, estimated that approximately 7,109 of these OUD cases in Cabell and Huntington were directly or indirectly attributable to prescription opioids.[40]

35. Over 600 pregnant women in Cabell and Huntington have been admitted to treatment with OUD.[41]

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[37] 6/17/21 Trial Tr. (Holbrook) at 194; 5/7/21 Trial Tr. (Rader) at 31-32, 59.

[38] P-44211_00007 (2016 West Virginia Overdose Fatality Analysis).

[39] P-41850_00007 (Mayor's Office of Drug Control Policy, Strategy Plan 2017); DEF-WV-02653, 00080 (City of Solutions; Huntington, WV); 5/21/21 Trial Tr. (Werthammer) at 20:9-20.

[40] 6/11/21 Trial Tr. (Keyes) at 212; 6/14/21 Trial Tr. (Keyes) at 160, 175.

[41] 6/16/21 Trial Tr. (Young) at 34.

36. Opioid Use Disorder has become so pervasive in the community that church pastors in Huntington have had to develop skills necessary to help families of addicted persons.[42]

C. Growth of Heroin and Illicit Fentanyl Use in Cabell and Huntington

37. Prescription opioid drugs and heroin have the same molecular structure and interact identically with and are received by the human brain as indistinguishable from one another.[43]

38. The new population of people in the region addicted to prescription opioids thus were primed for dependence on heroin and illicit fentanyl if and when their access to prescription opioids was disrupted, as occurred in and after 2011.[44]

39. As the Huntington Police Department observed, the costs associated with supply and demand for prescription drugs increased between 2011 and 2014 so that addicted persons began seeking out cheaper alternatives like heroin.[45]

40. Heroin and illicit fentanyl abuse in Cabell and Huntington started increasing in or around 2012, when the Huntington Police Department identified the growing use of heroin as one of the two biggest threats to the city, along with continued diversion and abuse of prescription opioids.[46]

41. In 2012, the Huntington Police Department determined that people who developed opiate addiction due to abuse of prescription medications would turn to heroin due to its lower price and availability. By 2013, heroin distribution in Huntington had grown significantly, which

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[42] 6/30/21 Trial Tr. (Williams) at 64.

[43] *See* 5/4/21 Trial Tr. (Waller) at 71-72.

[44] *See* 5/4/21 Trial Tr. (Waller) at 204; MC-WV-02079, 00006 (pg. 135) (Compton and Jones, *The Epidemiology of the U.S. Opioid Crisis: The Importance of the Vector*).

[45] 6/17/21 Trial Tr. (Holbrook) at 219-20, 241-42; P-41527_00008, 00011 (2014 HPD Threat Assessment).

[46] P-41347_00017, 00033 (2012 HPD Annual Report).

the Police Department found was directly linked to the predominant use of prescription opioids in the Appalachia region.[47]

42. Over the next few years, heroin and fentanyl abuse grew from being approximately 10% to being a substantial majority (60-70%) of drug abuse cases.[48]

43. By 2014, the Huntington Police Department considered heroin use to be the number one threat to public health and safety in the City, contributing to a significant rise in the number of overdose cases.[49]

D. Sharp Increase in Opioid-Related Mortality in Cabell and Huntington

44. Before the opioid epidemic, it was rare for police officers and firefighters in Cabell and Huntington to see a dead body. But with the sharp increase in opioid abuse came a rise in first responders being called to scenes of overdose deaths, sometimes seeing multiple overdose fatalities in a single day.[50]

45. Plaintiffs' epidemiology and drug overdose expert, Dr. Gordon Smith, testified that from 2001 to 2018, there were 1,002 opioid-related deaths in Cabell County, which represents almost 90% of all drug-poisoning deaths in the County during that period.[51]

46. In 2015, Huntington's drug overdose rate was 116 deaths per 100,000 population, which was the highest in the nation.[52]

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[47] *See* P-41347_00003, 00006 (2012 HPD Threat Assessment); 6/17/21 Trial Tr. (Holbrook) at 221-222; P-41527_00012 (2014 HPD Threat Assessment).

[48] 5/27/21 Trial Tr. (Zerkle) at 92:13-93:21.

[49] P-41220_00018 (2014 HPD Annual Report).

[50] 5/27/21 Trial Tr. (Zerkle) at 94; 5/ Trial Tr. (Rader) at 31-32, 54.

[51] 6/10/21 Trial Tr. (Smith) at 134.

[52] 6/11/21 Trial Tr. (Keyes) at 201.

47. From 2001 through 2011, prescription opioid deaths significantly exceeded heroin deaths in Cabell County.[53]

48. After 2011, prescription opioid deaths leveled off at a historically high level, while deaths from illicit opioids like heroin and fentanyl dramatically increased.[54]

49. In Cabell, Raleigh, and Kanawha Counties, there were 631 heroin-related deaths from 2011 to 2015, which represented a 78% increase over the previous ten years.[55]

50. Mortality from overdoses of illicit fentanyl, fentanyl analogues, and other illicit synthetic opioids in the drug supply rose over 20% in West Virginia between 2012 and 2017.[56]

51. The county-level distribution of fentanyl-related overdose deaths showed greater concentration in the southern West Virginia counties, as also has been the pattern with overdose deaths in West Virginia. Both frequency and rates per 100,000 for fentanyl-related deaths were concentrated in the southern counties, with 69% of fentanyl-related deaths from 2001 to 2015 being reported from Cabell and Kanawha Counties. In 2015, Cabell County accounted for 41% of fentanyl-related deaths in West Virginia.[57]

52. Prescription opioids remain to this day an ongoing and significant cause of drug overdose deaths in Cabell and Huntington, with preliminary data showing sharp increases in opioid-related deaths throughout West Virginia in 2019 and 2020.[58]

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[53] 6/10/21 Trial Tr. (Smith) at 138.

[54] 6/10/21 Trial Tr. (Smith) at 136-139.

[55] P-41213_00011 (2001-2015 West Virginia Drug Overdose Deaths, Historical Overview).

[56] 6/10/21 Trial Tr. (Smith) at 138-39.

[57] P-41213_00015 (2001-2015 West Virginia Drug Overdose Deaths, Historical Overview).

[58] 6/10/21 Trial Tr. (Smith) at 141, 153-54.

E. Neonatal Abstinence Syndrome in Cabell and Huntington

53. The opioid epidemic public health morbidities (non-fatal harms) in Cabell and Huntington include babies being born with neonatal abstinence syndrome ("NAS").[59]

54. Babies born with NAS need treatment for at least 20 to 30 days, and sometimes up to 100 days, and continue thereafter to suffer from diminished capacity and require special services.[60]

55. Even infants exposed to opioids who are not diagnosed with NAS have been found to suffer adverse developmental effects. Published literature shows that prenatal exposure to opioids increases distress, causes developmental delays, lowers IQ and educational and attainment scores, and results in the need for neuropsychiatric treatment and special education services.[61]

56. Pregnant mothers suffering from OUD give rise to a new series of harms related to addiction. Mothers have to address their own OUD through pregnancy and deliver a child who will likely suffer from NAS and require extensive neonatal care and later interventions.[62]

57. In 2012, one-third of Cabell and Huntington Hospital NICU patients were babies withdrawing from opioids.[63]

58. The rate of babies being born with NAS at Cabell and Huntington Hospital has been as high as 10%.[64]

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[59] 6/16/21 Trial Tr. (Yingling) at 157.

[60] 5/21/21 Trial Tr. (Werthammer) at 16-18.

[61] 6/16/21 Trial Tr. (Young) at 58-59, 62.

[62] 6/16/21 Trial Tr. (Yingling) at 162.

[63] 5/21/21 Trial Tr. (Werthammer) at 14.

[64] 5/21/21 Trial Tr. (Werthammer) at 16-18.

59. Approximately 2,500 babies born in Cabell and Huntington have been diagnosed with NAS.[65]

60. The incidence of NAS in Cabell County, 62.3 per 1,000 hospital births, is almost nine times higher than that in the United States as a whole (7 per 1,000).[66]

F. Impact on Children and Family Services in Cabell and Huntington

61. The opioid epidemic's harms include disruption and separation of families and children.

62. The number of children in West Virginia placed into foster care doubled over a ten-year period during the opioid epidemic, with 80% of placements involving substance abuse issues.[67]

63. In Cabell County, overdose deaths and foster care entries exceeded the national averages, resulting in demand for child placements not being met and increased placements outside of extended family, which has adverse effects on the child's intellectual, social, and emotional development.[68]

64. Childhood trauma resulting from placement into the foster care system requires special services to address the effect of displacement and for the child not to be defined by their parents' addiction.[69]

[65] 5/21/21 Trial Tr. (Werthammer) at 16-18.

[66] 6/11/21 Trial Tr. (Keyes) at 202-03; 5/21/21 Trial Tr. (Werthammer) at 18.

[67] 6/16/21 Trial Tr. (Young) at 42-43.

[68] 6/16/21 Trial Tr. (Young) at 19-22, 33, 41-46, 58-59.

[69] 6/16/21 Trial Tr. (Young) at 22-23.

65. Cabell County has had to expand its number of School Resource Officers from one to five and develop a new 24-hour communication line from police to schools for children whose parents are affected by substance abuse issues.[70]

66. Childhood trauma associated with loss of family of origin due to substance abuse will impact generations of families.[71]

67. This impact can include the intergenerational transmission of addiction, as having a parent or household member with substance abuse disorder is a significant risk factor for a child to develop addiction.[72]

68. Huntington Fire Department Chief Jan Rader testified about the family harms from addiction and overdose that she has seen up close in her work as Fire Chief:

> Comforting a mother, or a father, or a brother, or a sister, or a child, you know, we don't have the training for that, but there's a lot of carnage left behind from an overdose.
>
> There's a ripple effect. Your first responders are affected. Your family's affected. Some kids lose a parent to jail, maybe they die, they go into the foster care system. You have grandparents raising children of their children and maybe even a great.
>
> So it's just –it's widespread. You know, the school system, teachers deal with children that are being raised in environments where they are struggling, they're not able to eat regularly, things like that. It just goes on and on and on. A lot of carnage.[73]

[70] 5/27/21 Trial Tr. (Zerkle) at 106-107.

[71] 6/16/21 Trial Tr. (Yingling) at 162-64.

[72] 6/28/21 Trial Tr. (Alexander) at 49-50.

[73] 5/7/21 Trial Tr. (Rader) at 42.

G. Infectious Diseases in Cabell and Huntington

69. The opioid epidemic's harms in Cabell and Huntington include sharply increased rates of infectious disease, including HIV, Hepatitis B and C, and complications due to Endocarditis.[74]

70. Injection drug use introduces foreign organisms into the bloodstream, causing blood-borne infections that have high mortality and morbidity and are a substantial part of the public health crisis of the opioid epidemic.[75]

71. For people who inject drugs, there is a 1 in 160 chance of acquiring HIV with each injection, and an increasing risk with every additional injection.[76]

72. This makes injection drug use the second most common way that HIV is contracted.[77]

73. In 2019, there were 69 new cases of HIV in Cabell County, of which 90% were among people who inject drugs.[78]

74. HIV can be treated and managed by medication, which the patient must take daily for the rest of their life.[79]

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[74] 6/16/21 Trial Tr. (Yingling) at 156-158.

[75] 6/17/21 Trial Tr. (Feinberg) at 109, 112.

[76] 6/17/21 Trial Tr. (Feinberg) at 115.

[77] 6/17/21 Trial Tr. (Feinberg) at 115.

[78] 6/17/21 Trial Tr. (Feinberg) at 117.

[79] 6/17/21 Trial Tr. (Feinberg) at 119.

75. Hepatitis C is even more contagious than HIV among injection drug users, with approximately 40% of injection drug users contracting Hepatitis C in their first year of us and 90% eventually contracting it.[80]

76. As a result, West Virginia has for the past two decades been among the top two or three states for rate of Hepatatis C infection, while the rate in Cabell County is far higher still, reaching a rate of 10.3 cases per 100,000 people, which is more than double West Virginia's already-high statewide rate of 5.1 cases per 100,000 people.[81]

77. Hepatitis B, too, is highly associated with injection drug use and, as a result, West Virginia has had the highest Hepatitis B rates in the United States for over a decade.[82]

78. At present, the incidence of Hepatitis B in West Virginia is 14 times the national average,[83] while Cabell County has among the highest rates of Hepatitis B infections among West Virginia's counties, measuring 17 cases per 100,000 people in 2016.[84]

79. Endocarditis is most commonly caused by the injection of bacteria through the skin.[85] Although Endocarditis is not actively surveilled, a recent study across four West Virginia hospitals that included two in Cabell and Huntington showed that a significant proportion of the 762 Endocarditis cases observed is concentrated among people living in or near Cabell and Huntington.[86]

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[80] 6/17/21 Trial Tr. (Feinberg) at 128-29, 133.

[81] 6/17/21 Trial Tr. (Feinberg) at 129-30.

[82] 6/17/21 Trial Tr. (Feinberg) at 135-36.

[83] 6/17/21 Trial Tr. (Feinberg) at 136.

[84] 6/17/21 Trial Tr. (Feinberg) at 136.

[85] 6/17/21 Trial Tr. (Feinberg) at 140.

[86] 6/17/21 Trial Tr. (Feinberg) at 144.

H. The Opioid Epidemic's Toll on Cabell and Huntington's Communities

1. Demands on Government and Communities

80. Cabell County's budget and government services have been severely impacted by the opioid epidemic. The County Sheriff's Office had to address a sharp increase in the number of people incarcerated for addiction-related crimes, while the County as a whole faced a $3.3 million deficit and had to cut expenditures by ten percent in 2017.[87]

81. The City of Huntington's budget, too, has been directly impacted by the opioid epidemic. The City has used and continues to use human power, resources, and time to fight the opioid epidemic, which adversely affects both the City's budget and its ability to address other matters.[88]

82. The Huntington Police Department in 2011 identified lethal diversion of pain medications as the most prevalent threat to the community, [89] and by 2016 found that drug offenses and overdoses were occurring all over the City,[90] and in all types of places, from restaurants to doctor's offices to parks to abandoned homes.[91]

83. This was in sharp contrast to just ten years earlier, when only a small part of the City experienced drug offenses.[92]

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[87] 5/27/21 Trial Tr. (Zerkle) at 98-99.

[88] 6/30/21 Trial Tr. (Williams) at 140-43, 183-84.

[89] 5/21/21 Trial Tr. (Lemley) at 127.

[90] 5/21/21 Trial Tr. (Lemley) at 147, 153-54.

[91] 5/7/21 Trial Tr. (Rader) at 58.

[92] 5/21/21 Trial Tr. (Lemley) at 173-74.

84. As a result of this spread in drug-related crime, many residents live in fear as they see the impact of the opioid epidemic sweep through and bring down their neighborhoods.[93] Entire neighborhoods have been devastated with homes burnt out and abandoned.[94] The daily presence of people suffering from OUD in the community results in residents avoiding Huntington businesses because of fear of encountering homeless addicts.[95]

85. The epidemic has also decimated the workforce in Cabell and Huntington because of a shortage of workers who can pass a drug test.[96] The presence of an addicted workforce and the communities' reputation as the epicenter of the opioid epidemic has negatively impacted economic development efforts and diminished the tax community tax base.[97]

86. Huntington's Fire Department Chief likewise observed overdoses skyrocket in and after 2012, to the point that her department responded to more calls about overdoses in 2017 than it did to total rescue calls in 2010.[98]

87. The increased need to respond to overdose emergencies also means that first responders are less able to address other needs in the community.[99]

[93] 6/30/31 Trial Tr. (Williams) at 44.

[94] 5/27/21 Trial Tr. (Zerkle) at 119-20.

[95] 5/27/21 Trial Tr. (Zerkle) at 120.

[96] 5/27/21 Trial Tr. (Zerkle) at 119.

[97] 5/27/21 Trial Tr. (Zerkle) at 119.

[98] 5/7/21 Trial Tr. (Rader) at 31-33.

[99] 5/27/21 Trial Tr. (Zerkle) at 107, 111, 116-17.

2. Law Enforcement—Crime and Public Safety

88. The Huntington Police Department has seen the City being decimated by addiction, an explosion of opioid seizures, and a dramatic increase in property crime like break-ins tied to addiction, leading the Department to identify addiction as the greatest threat to the community.[100]

89. Cabell County also saw a surge in prostitution, breaking and entering, petit larceny, and shoplifting, as well as burglary, theft, disorderly conduct, and driving under the influence.[101]

90. The increases in drug abuse, drug crime, and property crime all stemmed from addiction in the community, of which opioid addiction was the driving force.[102]

91. Between 2007 and 2014, Huntington became known as a hub for illegal drug distribution, with the emergence of drug-trafficking operations in the City showing the widespread extent of addiction and demanding increased police attention.[103]

92. As a result, the Huntington Police Department has engaged in significantly increased numbers of drug seizures, occurring both in planned raids on pill mills and in increasing numbers of traffic stops.[104]

3. Compassion Fatigue

93. The opioid epidemic is taking a toll on police officers and other first responders who have had to address the effects of a community filled with addiction, making them feel

[100] 6/17/21 Trial Tr. (Holbrook) at 198-99, 220.

[101] 5/27/21 Trial Tr. (Zerkle) at 99-100, 184-85.

[102] 6/17/21 Trial Tr. (Holbrook) at 220; *id.* at 192, 197 (robberies), 199 (break-ins); *see also* Brown, 5/17/20 30(b)(6) Dep. at 271-72 (HIDTA survey of law enforcement, linking prescription drugs to violent crime and property crime).

[103] 6/17/21 Trial Tr. (Holbrook) at 230, 242.

[104] 5/21/21 Trial Tr. (Lemley) at 135; 6/17 Trial Tr. (Holbrook) at 195, 220; 5/27 Trial. Tr. (Zerkle) at 85, 89.

helpless as they respond to overdose call after call, sometimes involving the same people, whom the first responders see deteriorating over time.[105]

94. Overdose scenes are chaotic and mentally challenging for first responders, who often have to help the victim and console the victim's loved ones, such as a child who is watching as their parent is revived.[106]

95. Huntington firefighters have suffered from post-traumatic stress disorder and compassion fatigue from being called to these scenes, which often involve friends, classmates, and other acquaintances from the community.[107]

96. Due to the level of overdoses in the community, all first responders now carry naloxone.[108] The Cabell County Health Department provides weekly training on Naloxone and the CCSAPP focuses on providing information to school age children about Naloxone.[109]

97. Law enforcement and first responders have been exposed to trauma above and beyond the usual experience of their already-demanding jobs, including by facing the risk of personal airborne exposure to fentanyl.[110]

98. Repeated exposure to traumatic experiences, such as multiple overdoses and overdose-related deaths among young people, impact emergency responders emotionally,

[105] P-41221_00001 (2015 HPD Annual Report); 5/7/21 Trial Tr. (Rader) at 54.

[106] 5/7/21 Trial Tr. (Rader) at 35.

[107] 5/7/21 Trial Tr. (Rader) at 41-42.

[108] 5/7/21 Trial Tr. (Rader) at 35.

[109] DEF-WV-0002653 (City of Solutions), 00056.

[110] 5/2721 Trial Tr. (Zerkle) at 95-96; 97-98; 125-27.

behaviorally, interpersonally, and physically, resulting in increased personnel turnover and decreased personal empathy.[111]

4. Costs of the Opioid Epidemic in Cabell and Huntington

99. The opioid epidemic's mortalities include lives lost, lost companionship, lost family, and lost parental support.[112]

100. In West Virginia, the highest number of opioid overdose deaths occur between ages 35 and 54 years old, *i.e.* to "average working age West Virginians in the prime of their life."[113]

101. The White House Council of Economic Advisors has placed a value of a statistical life ("VSL") of $9.3 million (in 2014 dollars) per life lost to the opioid epidemic. Plaintiffs' health economics expert, Dr. Thomas McGuire, testified that the adjusted VSL for lives lost in Cabell and Huntington due to prescription opioids is $2.8 billion.[114]

102. The total excess healthcare cost for prescription-related OUD in Cabell and Huntington from 2006 to 2018 is $494 million.[115]

103. The total mortality and morbidity harms-related cost due to prescription opioids in Cabell and Huntington is in excess of $3.2 billion.[116]

104. The Court therefore finds that the opioid epidemic in Cabell and Huntington constitutes an unreasonable, significant, long-lasting, and continuing interference with the public

[111] 5/6/21 Trial Tr. (Priddy) at 198-201; 5/7/21 Trial Tr. (Rader) at 41-42, 54-55; 5/21 Trial Tr. (Lemley) at 133-34; 5/27/21 Trial Tr. (O'Connell) at 211-12.

[112] 6/16/21 Trial Tr. (Yingling) at 158, 162.

[113] 5/5/21 Trial Tr. (Gupta) at 79-80.

[114] 6/17/21 Trial Tr. (McGuire) at 28-32.

[115] 6/17/21 Trial Tr. (McGuire) at 28-32.

[116] 6/17/21 Trial Tr. (McGuire) at 31-32.

health, public safety, public peace, public comfort, and public convenience of the County and City's communities.

II. Defendants Acted Unreasonably in Contributing to an Immense Oversupply of Prescription Opioids in Cabell and Huntington.

105. The Court further finds based on the conduct set forth below that each Defendant—ABDC, Cardinal, and McKesson—acted unreasonably in failing to maintain adequate or effective controls against diversion of the prescription opioids they distributed, which contributed to the oversupply and diversion of tens of millions of highly addictive opioid pills into Cabell and Huntington as these communities struggled with the horrific opioid epidemic harms set forth above.

106. Defendants' actions thwarted the Controlled Substances Act's purpose to create a self-policed closed system of controlled substances distribution to protect against diversion. The closed distribution system cannot work without accountability of all members within the closed system, in which Defendants and other distributors play a central part.[117]

107. The 2008 Industry Compliance Guidelines developed by Defendants and their trade association, the Healthcare Distribution Alliance ("HDA"), makes clear Defendants' role in the closed system:

> At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support security of controlled substances

[117] Hartle, 7/31/2018 30(b)(6) (McKesson) Dep. at 294:15-295:5 (discussing P-00003 (Prescription Drug Abuse: The National Perspective – McKesson Powerpoint Presentation), Q. Page 8, the Controlled Substances Act, the very last provision says, "Creates checks and balances between registrants to protect the public health and safety." Again, this is again a reaffirmation from Gary Boggs, who is now one of your senior regulatory affairs management, acknowledging that the registrants and the DEA have a duty to protect the public health and safety, agreed? A. Agreed.); Norris, 8/7/18 30(b)(6) (Cardinal) Dep. at 77:9-15 ("The rules, as I understand them, are to ensure that the participants in the distribution system understand their obligations and operate within that distribution -- that closed distribution system, maintaining the security of the pharmaceuticals we distribute, the scheduled substances we distribute.")

> they deliver to their customers. Due Diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.[118]

Thus, by 2008, it was well-established and widely-recognized that the CSA required Defendants to control the supply chain by carefully conducting due diligence to prevent diversion of the opioid and other controlled substances orders they shipped.[119]

108. Defendants have sophisticated market schemes that they have used as part of their efforts to corner the controlled substances distribution market.[120] McKesson, Cardinal, and ABDC are long-time members of the HDA and are known in the industry as the "Big 3."[121] Collectively, Defendants distributed close to 90% of the prescription opioids in the United States by 2014.[122]

109. In 2016, the National Association of Drug Diversion Investigators acknowledged that, while there are around 800 wholesale distributors in the United States, "McKesson, Cardinal and AmerisourceBergen have a combined market share in excess of 90%."[123]

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[118] P-00629 (*admitted for purpose of showing notice*) (ABDCMDL00295006, Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion); *see also* P-00014_00019-22 (Sept. 2017 Controlled Substance Monitoring – Discount Drug Mart – McKesson Powerpoint Presentation) (describing the regulatory responsibility of the opioid supply chain).

[119] *Id.; see also*, Prevoznik, 5/17/19 30(b)(6) Dep. at 900:22-901:8 (Q. Okay. And if you look at the first page, the third paragraph: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." Do you see what I've just read? A. Yes. Q. And does the DEA agree with that statement? A. Yes.) (agreeing with ICG statement in P-00629 *supra*).

[120] 6/11/2021 Trial Tr. (Dr. Mohr) at 75:16-76:6.

[121] Gray, 7/30/20 Dep. Tr. at 21:22-19.

[122] Gray, 7/30/20 Dep. Tr. at 23:9-19.

[123] P-00898 (ABDCMDL00159071, Naddi Slides PPT).

110. Pursuant to their duties to maintain effective controls against diversion under the Controlled Substances Act ("CSA") and Drug Enforcement Administration ("DEA") regulations, each of the Defendants formally had Suspicious Order Monitoring ("SOMs") programs in place. But they failed in practice to follow the CSA's and DEA's requirements, or even those of their own programs.

111. Defendants committed these failures in the face of rising concerns over the abuse of diverted prescription opioid pills in West Virginia and greater Appalachia. Following Purdue Pharma's development and release of OxyContin in the 1990s, it quickly became the most prescribed brand-name narcotic in the country.[124]

112. In 2001, the U.S. Department of Justice ("DOJ") issued a warning about widespread diversion of OxyContin, which is referenced in a 2003 report of the U.S. Government Accountability Office ("GAO") on the same subject—*Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*.[125]

113. The GAO found that "media reports of OxyContin abuse and diversion began to surface in 2000[,]" as did reports about West Virginia specifically "being devastated by the abuse and diversion of OxyContin."[126] Such reports included the fact that, in 2000, as many as one-half of patients admitted to a drug treatment clinic in West Virginia were being treated for OxyContin addiction.[127]

114. Defendants have asserted that the volume of *all* prescriptions, opioid and non-opioid alike, dispensed in West Virginia is higher than other areas of the country. This factor,

[124] MC-WV-01764.00002.

[125] MC-WV-01764.

[126] MC-WV-01764.00014.

[127] MC-WV-01764.00015.

Defendants claim, contributes to and explains the disproportionately large volume of opioids distributed to West Virginia pharmacies. Certainly, these factors will impact the distribution volume coming into West Virginia, including Cabell Count and Huntington specifically.

115. But these factors alone cannot account for how West Virginia received more oxycodone pills than the entire state of Texas year after year over a nine-year period.[128] West Virginia received almost double the pills with a population one-thirteenth that of Texas. Combining this enormous volume of shipments with a lack of due diligence, a lack of reported suspicious orders, and failures to follow their own policies, Defendants' conduct cannot be explained solely or even primarily by the fact that West Virginia pharmacies may dispense higher numbers of prescriptions in general.

116. Instead, what happened is that Defendants seized upon the chance to increase sales, whether from legitimate or illegal prescriptions, and ignored all warning signs that they were fueling an opioid epidemic and oversupplying a region where diverted prescription pills severely impacted the health and safety of communities, including those of Plaintiffs herein.

117. Plaintiffs' evidence overwhelmingly demonstrates that Defendants behaved unreasonably in its distribution of dangerously addictive prescription opioids, thus providing the predicate culpable conduct for a finding of public nuisance. Given the dangerous and addictive nature of these drugs, it was necessary for Defendants to control their distribution and to take steps to prevent diversion for illegitimate purposes. Defendants created national policies that purported to provide tools to prevent diversion, through the identification of so-called "suspicious orders," those with indicia of diversion. But these tools were not, in fact, effective in preventing diversion

[128] P-44318_00001-00002 (U.S. Census Bureau, Population Distribution and Change: 2000 to 2010, March 2011).

and Defendants did not, in any event, seriously implement them. Its failure to control the supply chain for the dangerous drugs it was distributing was unreasonable and created a public nuisance, when inevitably and predictably, the drugs were diverted.

A. Defendants have long been on notice of their CSA duties.

118. As part of their duties to maintain effective controls against diversion under the CSA and DEA regulations, each Defendant has formally maintained Suspicious Order Monitoring programs ("SOMs"). In practice, however, Defendants knowingly failed to comply with either what the law required or even what their own programs required.

119. During 2006 and 2007, due in part to Defendants' continued failure to comply with their regulatory obligations, DEA sent three letters by its Deputy Assistant Administrator for the Office of Diversion Control, Joseph Rannazzisi, to Defendants and other registrants across the country. The Rannazzisi letters outlined Defendants' legal obligations to conduct due diligence, report suspicious orders, and avoid filling suspicious orders.[129]

120. The September 27, 2006 letter was sent to all distributors and manufacturers after DEA had held a series of Distributor Initiative Meetings with Defendants.[130] The letter "reinforces both what was in the distributor initiative, and it provides information concerning obligations under the Controlled Substances Act[131] relating to suspicious order monitoring."[132] The letter advised that a distributor could not rely on a customer's registration as a substitute for performing due diligence.[133] The letter was not a new interpretation of the CSA and was consistent with prior

[129] P-00032 (June 2012 Dear Registrant Letter) ; *see also* 6/8/21 Trial Tr. (Rannazzisi) at 115-16.

[130] *See* 6/8/21 Trial Tr. (Rannazzisi) at 60.

[131] 21 U.S.C. §§ 801 *et seq.*

[132] 6/8/21 Trial Tr. (Rannazzisi) at 116.

[133] P-00032_00010 (June 2012 Dear Registrant Letter) .

DEA guidance.[134]

121. The 2006 letter provided specific guidance on the characteristics often displayed by pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose and provided a list of questions a distributor investigating a suspicious order might ask. Specifically, the DEA identified the following characteristics:

1. Ordering excessive quantities of a limited variety of controlled substances (*e.g.*, ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substances from multiple distributors.[135]

122. The DEA further offered lines of inquiry a distributor seeking to determine whether a suspicious order is indicative of diversion may wish to inquire about from the ordering pharmacy, including, *inter alia,* (1) percentage of controlled substance business; (2) compliance with laws of every state in which it is dispensing controlled substances; (3) is the pharmacy soliciting buyers of controlled substances via the internet or associated with an internet site; (4) does the pharmacy or affiliated internet cite offer to facilitate the acquisition of a prescription for a controlled substance

[134] 6/8/21 Trial Tr. (Rannazzisi) at 121; *see also* P-00032_00009 (June 2012 Dear Registrant Letter); *see also* Hartle 7/31/18 Dep. at 160-64 (Sept. 2006 Rannazzisi letter "was mostly a confirmation or a reiteration of the regulations, which McKesson knew…. So not significant changes that I'm aware of."; accurate on law); *see also* Prevoznik, 4/18/19 Depo at 761 (nothing in September 2006 Joe Rannazzisi letter is new), 661-65 (NWDA guidelines, 1990's, report suspicious order immediately; after-the-fact monthly printout insufficient), 695-96 (1996 DEA DIM, registrants who fill reported suspicious orders are jeopardizing public health and safety), *see also* Prevoznik, 5/17/19 Depo at 810-11 (DEA 1984 Gitchel ltr.—monthly report of after-the-fact sales not satisfy reporting duty; reporting "orders" means prior to shipment), 933-34 (Rannazzisi letters did not change the obligations of registrants); 6/8/21 Trial Tr. (Rannazzisi) at 121.

[135] P-00032_00011 (June 2012 Dear Registrant Letter).

form a practitioner with whom the buyer has no pre-existing relationship; (5) does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or a bona-fide doctor-patient relationship; (6) are the prescribing physicians licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped; (7) are one or more practitioners writing a disproportionate share of the prescriptions being filled by the pharmacy; (8) does the pharmacy offer to sell controlled substances without a prescription; (9) does the pharmacy charge reasonable prices for controlled substances; (10) does the pharmacy accept insurance payment for purchases of controlled substances made via the internet.[136] The DEA specifically noted "these questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances."[137]

123. The 2006 letter further advised:

> DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants, manufacturers, distributors, pharmacies, and practitioners, share responsibility for maintaining appropriate safeguards against diversion. *Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.* Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.
>
> …
>
> Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

[136] *Id*.

[137] *Id.*

> …
>
> In a similar vein, given the requirement under Section 823(e) that a distributor maintain effective controls against diversion, *a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances*.
>
> …
>
> Again, to maintain effective controls against diversion as Section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.[138]

124. The DEA's February 7, 2007 and December 27, 2007 letters by Mr. Rannazzisi again reminded distributors that in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid *filling* suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.[139] The December 2007 letter further noted: "[f]iling a monthly report of completed transactions (*e.g.*, "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders.[140] The DEA also told ABDC in letters and briefings that "Excessive Order Reports" (which all three Defendants were sending to the DEA) were not equivalent to suspicious order reports.[141]

125. The DEA's December 2007 letter also emphasized:

> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one

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[138] 6/8/21 Trial Tr. (Rannazzisi) at 117-19 (reading from P-00032, June 2012 Dear Registrant Letter).

[139] Among other guidance, the DEA's December 27, 2007, letter also instructed registrants to review the final order issued by the DEA in the matter of *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007), regarding their legal obligations to report suspicious orders. *See* P-02027 (Dec. 2007 DEA Dear Registrant Letter); *see also* 6/8/21 Trial Tr. at 151-52 (DEA's 2007 *Southwood* decision, know-your-customer duty, red flags of diversion; no-ship duty).

[140] P-00032 (June 2012 Dear Registrant Letter); 5/13/21 Trial Tr. (Zimmerman) at 39-40.

[141] 6/7/21 Trial Tr. (Rannazzisi) at 228, 229-30, 231, and 233.

> month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributors. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviated from the normal pattern of what pharmacies generally order.[142]

126. The DEA further advised that "registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion."[143]

127. The December 2007 letter reiterated that the DEA did not approve or otherwise endorse any specific system of reporting suspicious orders.[144] It also specifically provided notice that any prior implicit or explicit suggestions that the DEA had approved systems in the past were revoked.[145]

128. Defendant ABDC has admitted that the December 2007 letter to Defendants and all registrants provided guidance that when looking for suspicious orders, a distributor should look for ordering patterns from a particular customer and should also compare the ordering patterns of a particular customer throughout the relevant segment of the regulated industry.[146]

129. In separate written agreements with the DEA, AmerisourceBergen (2007) and Cardinal and McKesson (2008) agreed "to maintain a compliance program designed to detect and

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[142] P-02027 (Dec. 2007 DEA Dear Registrant Letter) ; 6/8Trial Tr. (Rannazzisi) at 145 (formula-based SOM may miss suspicious orders)

[143] P-00032 (June 2012 Dear Registrant Letter); 5/13/21 Trial Tr (Zimmerman) at 44-45.

[144] *Id*. at 3; 5/13/21 Trial Tr (Zimmerman) at 38.

[145] *Id*. at 3; 5/13/21 Trial Tr (Zimmerman) at 38-39.

[146] 5/12/21 Trial Tr. (Zimmerman) at 41, 44.

prevent diversion of controlled substances" as required under the CSA and applicable DEA regulations.[147]

130. Defendants, however, systematically failed to comply with these duties, as is set forth below with respect to each individual Defendant.

B. ABDC

1. ABDC's Order Monitoring Program and Anti-Diversion Policies

a. ABDC's Pre-2007 Policies

131. ABDC has a nationwide distribution model and nationwide policies governing compliance with the CSA, and those policies were to be implemented uniformly across the country. [148]

132. During the 1990's, ABDC order-fillers (who worked in the vault at its distribution centers) had the responsibility for "knowing the orders that they fill and, if they have any suspicion . . . depending upon what they *feel*, they have an obligation to report it, which resulted in 12,000 phone calls" a year.149 These employees had no background in compliance nor guidance on how to identify potentially suspicious orders and were not equipped to prevent diversion, particularly based on naked observation or instinct.[150]

133. ABDC set customer "thresholds," solely size-based triggers for suspicion or investigation, by calculating an average volume of sales for different categories of customers *and*

[147] *See* P-23733 (2008 DEA-McKesson Settlement and Release Agreement and Administrative Memo of Agreement).

[148] 5/12/21 Trial Tr. (Zimmerman) at 189.

[149] 5/13/21 Trial Tr. (Zimmerman) at 47-48 (emphasis added).

[150] 5/13/21 Trial Tr. (Zimmerman) at 51-52 (order-fillers were cited the "Code of Federal Regulations" as to whether an order is suspicious).

then applying a multiplier of three,[151] so that the threshold would not be reached unless an order was at least three-times over average. Until 1998, ABDC was comparing all pharmacies together in one category, taking an average and identifying anything over the average as suspicious, which resulted in large customers getting reported frequently and smaller customers never getting reported, even if the pattern, volume, or frequency of their orders changed dramatically.[152]

134. In 1998, ABDC began comparing the customer to itself, rather than to all other pharmacies.[153] But it set the threshold to flag an order so high that it was unable to detect gradual increases in diversion. For example, if a customer's previous three-month average was 1,000 pills, a pharmacy could order 3,000 pills the next month before ABDC's system would even flag it as suspicious.[154] ABDC's system did not consider the frequency or pattern of orders that should have allowed it to make informed decisions to investigate and cancel certain shipments to its pharmacy customers that the governing regulations defined as suspicious.[155]

135. Prior to 2007, any order that exceeded ABDC's threshold calculation was deemed excessive and simply reported to the DEA as an Excessive Order Report.[156] During this time, ABDC's policy was to ship all orders, regardless of whether they were reported to the DEA as excessive.[157] ABDC's pre-2007 SOMs policies were so inadequate that, in 2007, DEA issued an

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[151] P-00082 at 2 (1999 Bergen Brunswig Regulatory Compliance and Security Services Policy and Procedures document – "monthly average times factor for ARCOS items is presently set by DEA at three times the monthly average"); 5/13/21 Trial Tr (Zimmerman) at 54, 60-61.

[152] 5/13/21 Trial Tr. (Zimmerman) at 54.

[153] 5/13/21 Trial Tr. (Zimmerman) at 54.

[154] 5/13/21 Trial Tr. (Zimmerman) at 55, 58.

[155] 21 CFR 1301.74(b).

[156] 5/13/21 Trial Tr (Zimmerman) at 54, 60-61.

[157] 5/13/21 Trial Tr. (Zimmerman) at 45 (pre-2007, ABDC shipped suspicious orders).

Immediate Suspension Order against ABDC, which stopped it from distributing controlled substances pending an administrative hearing,[158] for its systematic failure to maintain effective controls against diversion. DEA required ABDC to substantially improve its suspicious order monitoring Program but the new program – known as the Order Monitoring Program, or OMP – remained inadequate to detect and identify suspicious orders.[159]

b. ABDC's Post-2007 Policies

136. As result of its 2007 Immediate Suspension Order and resulting settlement with the DEA,[160] ABDC revised certain components of its threshold system. Specifically, its revised threshold system grouped customers by DEA classification (*i.e.* hospital, retail pharmacy, practitioner, or distributor) and subclasses (small, medium, large) based on the total dollar value of prescription sales.[161] ABDC used a national average of each customer group's purchases and, as before, multiplied that average by three to develop a threshold.[162] From 2007 to 2014, ABDC's suspicious order threshold was based on a national average of customers.[163] During that same time period, ABDC's program did not consider a pharmacy's local population, local total sales volume, or other local circumstances,[164] such as the presence and extent of diversion and addiction.

[158] 6/8/21 Trial Tr. (Rannazzisi) at 29.

[159] 5/12/21 Trial Tr. (Zimmerman) at 228; P-00877.

[160] Findings of Fact ("FOF"), *infra*, ¶¶ 164-65.

[161] 5/13/21 Trial Tr. (Zimmerman) at 54, 223-226; 5/17/21 Trial Tr. (Mays) at 203-04; P-00432 (01/19/2009 memo from Hazewski, Krueztner and Tomkiewicz to Zimmerman re. RVP Talking Points);

[162] 5/18/21 Trial Tr. (Mays) at 133 (threshold system 2007-14 was simply three times the national average).

[163] 5/18/21 Trial Tr. (Mays) at 34-35.

[164] 5/17/21 Trial Tr. (Mays) at 203-05.

137. In 2007, ABDC finally adopted a policy to block suspicious orders.[165] ABDC's new policy was to hold orders that exceeded a customer's threshold and not ship them, pending review by its national Corporate Security and Regulatory Affairs ("CSRA") investigatory group – CSRA Review.[166] The distribution center could release an order if it felt comfortable releasing based on the knowledge of the customer; if the distribution center did not clear the order, it was sent to corporate for review.[167] Those orders were supposedly not to be shipped unless the suspicion was resolved.[168] The process did not get triggered unless the computer flagged the order.[169] Held orders went into a queue via a messaging system to be reviewed.[170]

138. In 2009, ABDC's monthly default thresholds for small accounts ("total monthly dollar volume <$100K") were set for oxycodone at 12,366 and hydrocodone at 18,480.[171] For medium accounts ("total monthly dollar volume $100 K-$249,999") the threshold for oxycodone

[165] 5/13/21 Trial Tr. (Zimmerman) at 71; P-26293 (Dec. 1, 20065 ABDC Possible Excessive/Suspicious Order Review Policies and Procedures) .

[166] 5/13/21 Trial Tr. (Zimmerman) at 76 (ABDC OMP, Oct. 2008, if order flagged as suspicious, customer cut off until resolved); 79-82, 222 (ABDC memo, June 2007, customer exceed monthly threshold, reject further sale of like items until customer cleared)

[167] 5/17/21 Trial Tr. (Mays) at 215.

[168] 5/17/21 Trial Tr. (Mays) at 215; Ed Hazewski, 10/25/18 Depo at 60 (to thoroughly investigate suspicious orders it was necessary to determine whether or not there was a reasonable explanation for a flag).

[169] 5/17/21 Trial Tr. (Mays) at 216.

[170] 5/18/21 Trial Tr. (Mays) at 74-76.

[171] P- P-00432 (01/19/2009 memo from Hazewski, Krueztner and Tomkiewicz to Zimmerman re. RVP Talking Points) ; 5/13 Trial Tr. (Zimmerman) at 223-224.

was 24,732 and hydrocodone was 39,960.[172] For large accounts ("total monthly dollar volume >$250K") the threshold for oxycodone was 37,098 and hydrocodone was 55,440.[173]

139. Under the 2009 default thresholds, a small pharmacy could order 350,000 dosage units of hydrocodone and oxycodone a year without triggering the thresholds and ABDC's order monitoring process.[174] A medium-sized pharmacy could order 760,000 dosage units of hydrocodone and oxycodone a year without triggering the thresholds and ABDC's order monitoring process.[175] A large pharmacy could order over a million dosage units of hydrocodone and oxycodone a year without triggering the thresholds and ABDC's order monitoring process.[176] ABDC also warned its pharmacy customers when they were approaching their monthly thresholds.[177] This strongly suggests that ABDC intended for these thresholds to create the appearance that it had a meaningful Suspicious Order Monitoring System, while the system in practice did very little to detect or prevent shipment of orders of unusual size, pattern, or frequency.

c. ABDC's Due Diligence Programs

140. As part of its OMP, and as a result of the DEA's 2007 Immediate Suspension Order,[178] ABDC implemented a "Know Your Customer" due diligence program.[179] ABDC implemented its Know Your Customer due diligence program using its Form 590, which was used

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[172] *Id.*

[173] *Id.*

[174] 5/13/21 Trial Tr. (Zimmerman) at 225; *see also* P-00432 (01/19/2009 memo from Hazewski, Krueztner and Tomkiewicz to Zimmerman re. RVP Talking Points) .

[175] *Id.*.

[176] 5/13/21 Trial Tr. (Zimmerman) at 226; *see also* P-00432(01/19/2009 memo from Hazewski, Krueztner and Tomkiewicz to Zimmerman re. RVP Talking Points) .

[177] Hazewski, 10/25/18 Depo at 123-125.

[178] FOF, *infra*, ¶¶ 164-65.

[179] 5/18/21 Trial Tr. (May) at 44-48.

to collect and track information on pharmacy customers.[180] ABDC had not been collecting due diligence data prior to 2007 and did not go back and conduct due diligence on existing customers.[181] In July 2016, ABDC launched a formal "CSRA Form 590 Validation Project" to obtain due diligence documentation for every customer authorized to purchase controlled substances.[182] The first phase of this project involved conducting "a full review of every ABDC customer authorized to purchase controlled substances and identify any with deficiencies."[183] After this review was conducted, "a substantial number of customers were identified who will be required to have their 590 documentation updated."[184] However, even though a substantial number of customers needed their due diligence documentation updated, ABDC's sales force's priority was "still the financial performance of your assignment."[185]

141. ABDC's sales team was responsible for performing on-site investigations for due diligence, was the "eyes and ears" of Regulatory Affairs, and collected information regarding potential red flags.[186] At the same time, ABDC offered sales representatives bonuses based on sales, and sales representatives could lose bonus amounts if a customer left ABDC.[187] In 2011, ABDC's Business Development Manager pushed back on cutting off a customer which had a

[180] 5/18/21 Trial Tr. (May) at 44-48.

[181] 5/14/21 Trial Tr. (May) at 48.

[182] P-41623 (1/16/2017 email from Ernsberger to Perry, McKinnon, Dowling, and others re: Action Item – 590 validation Project) .

[183] *Id*.

[184] *Id*.

[185] *Id*.; See also 5/19/21 Trial Tr. (Perry) at 166.

[186] 5/18/21 Trial Tr. (Mays) at 38; *see also* 5/19/21 Trial Tr. (Perry) at 91, 94, 103.

[187] Elkins, 11/14/18 Depo at 123-25, 131 (ABDC offered sales representatives bonuses based on sales numbers; the higher the number, the more you make) 160-61, 213 (sales representative could lose bonus amounts if customer leaves ABDC; total sales goal figure not adjusted)

100% increase in their oxycodone purchases between August and September with no corresponding rationale for the spike, recommending to "re-consider such harsh action."[188] Other personnel added that if ABDC followed through with cutting them off they would lose "a million dollars a month-12 million per year. My numbers can't handle that loss and I don't think ABC would want that type of loss either . . . We stand to lose these 2 customers and send a terrible message to the retail community in the entire region . . ."[189]

142. ABDC's local sales executive, Mike Perry, testified regarding an email from Nathan Elkins, describing a summer review of "all accounts with less than $50,000/month in volume" and "for any such accounts that were purchasing a high percentage of controlled substances in relation to their overall TRV [*total sales*], you were directed to have frank conversations reiterating the importance of diversion control and that any red flags caused by their purchasing patterns put them at risk of having controlled substance purchases suspended or limited by ABC."[190] Mr. Perry admitted that ABDC did not have these same frank conversations about diversion control with his pharmacy customers over $50,000 in Cabell and Huntington.[191]

i. <u>Due Diligence Programs for Chain Pharmacies</u>

143. ABDC imposed different, less rigorous rules on its chain pharmacy customers in its Know Your Customer program. Specifically, ABDC did not apply that program's due diligence requirements to chain pharmacies.[192] Instead of collecting due diligence information from each

[188] P-02504 (12/1/2011 email from Snyder to Miller, Hazewski, Franklin re: TN Customers).

[189] *Id* at 2.

[190] 5/19/21 Trial Tr (Perry) at 148-149; P-41622 (12/23/2013 email from Elkins to DeLong, Halls, Perry, Pitts, and Schrott re: Controlled Drug Monitoring Follow Up).

[191] *Id*..

[192] 5/19/21 Trial Tr. (Mays) at 38

pharmacy location of a retail chain, ABDC merely created a chain-wide spreadsheet.[193]

144. For example, ABDC permitted Walgreens to submit a single 590 spreadsheet for all of its stores, rather than requiring each store to provide the required information.[194]

145. ABDC also helped Walgreens to evade detection of suspicious orders by providing it with the store-specific thresholds ABDC set for its pharmacy locations.[195]

146. ABDC also offered pharmacy chains volume-based discount pricing, thus rewarding them for placing excessive orders rather than preventing this.[196]

ii. Due Diligence Programs for Local Pharmacies

147. ABDC currently maintains 27 distribution centers in the U.S.[197] Its distribution center in Lockbourne, Ohio (Columbus) is the primary distribution center for West Virginia.[198]

148. Safescript #6 is a retail pharmacy located in Huntington, West Virginia, and a prior customer of ABDC.[199] As detailed below, ABDC increased SafeScript's oxycodone thresholds to more than four times their initial level — from 10,600 dosage units per month before September 2007 to 45,000 dosage units per month in June 2009 — without meaningful due diligence.[200]

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[193] 5/17/21 Trial Tr. (May) at 174.

[194] 6/15/21 Trial Tr. (Keller) at 142.

[195] Hazewski, 10/25/18 Dep at 124-25. Hazewski testified that Mays was "trying to think of everything we can do to prevent having a bunch of [WAG] orders reported to DEA and held" *Id.* at 138.

[196] Elkins, 11/14/18 Depo at 77-80.

[197] 5/8/21 Trial Tr. (Zimmerman) at 149; *see also* 5/10/21 Trial Tr. (Mays) at 25.

[198] 5/8/21 Trial Tr. (Zimmerman) at 149-50; 5/9/21 Trial Tr. (Zimmerman) at 171.

[199] P-16639 (at row 40).

[200] P-16639; *see also* 5/18/21 Trial Tr. (Mays) at 78-87.

ABDC did not produce due diligence documents to justify any of these threshold increases.[201]

149. Flagged orders from July 2007 show that ABDC set SafeScript's oxycodone threshold at 10,600 doses per month.[202] However, in June 2007, ABDC shipped SafeScript 53,900 dosage units of oxycodone.[203] During its entire relationship with SafeScript, ABDC shipped the pharmacy less than three times the 10,600 threshold just once — in the pharmacy's first month with ABDC, when it purchased 28,700 doses of oxycodone.[204]

150. By September 2007, ABDC had increased SafeScript's threshold for Oxycodone Solid pills from 10,600 to 30,000 dosage units per month.[205] By July 2009, ABDC increased the monthly threshold to 45,000 dosage units of Oxycodone Solids.[206] According to ABDC's transactional data, these threshold increases resulted in SafeScript Pharmacy #6 receiving an average of 35,551 dosage units of oxycodone per month for over six years from January 2006 to February 2012.[207]

151. In 2009, Mr. Perry replied to an inquiry regarding SafeScript by the Lockbourne Manager of Regulatory Compliance, advising, "this account has always purchased a high volume

[201] P-16639 (illustrates SafeScripts' threshold increases). ABDC's discovery responses were entered into evidence and only consisted of several pages, none of which included justification for the increases in threshold which SafeScript received; P-23655 (ABDC's 4th Supp. Objections and Responses to Plaintiffs' 1st Comb. Discovery Requests.

[202] P-16639.

[203] P-16639.

[204] P-16639.

[205] P-44766 (2007-2011 ABDC Reported Orders to DEA from WV at Row 470).

[206] P-44766 (2007-2011 ABDC Reported Orders to DEA from WV at Row 1647).

[207] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County).

of Controls to total sales. We have made adjustments to the Thresholds in the past due to this being the primary business at this account."[208]

152. In June 2011, ABDC's Order Monitoring Program flagged 24 SafeScript orders of oxycodone for exceeding its threshold.[209] On July 29, 2011, Mr. Perry requested an oxycodone threshold increase.[210] Although the threshold review form specifies that "exceeding the established threshold does not in itself justify a threshold increase in all cases," the justification for increasing the threshold was that the customer "has had issues with them exceeding the thresholds." [211] Mr. Perry admitted that there was no reason stated for the increase to the threshold.[212]

153. Despite this fact, the request for the threshold increase was approved.[213] Ed Hazewski responded, "The customer has been adjusted and is now set at the maximum they can receive of this product. Their CS ratio is 86% of their overall purchases."[214] For context, ABDC noted in January 2009 that the "average retail customer in our customer base has a CS ratio of about 12%."[215] The increase of SafeScript's threshold to an 86% CS ratio, without additional justification, indicates ABDC was not following its policy that "thresholds will remain firm for the appropriate customer size. No orders surpassing the threshold will be released and no

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[208] P-16655; 5/19 Trial Tr (Perry) at 124-125, 127-128.

[209] P-16639.

[210] P-16651 (7/29/2011 email from Perry to Hazewski re: Threshold Limits at Safescript Rx).

[211] *Id.; see also* 5/19 Trial Tr (Perry) at 129-131.

[212] 5/19 Trial Tr. (Perry) at 140-141.

[213] P-16642; 5/19 Trial Tr (Perry) at 142.

[214] P-16642; 5/19 Trial Tr (Perry) at 142; 5/19 Trial Tr (Perry) at 77-78 (A controlled substance ratio ("CS ratio") is the total sales amount of controlled substances over the total sales amount).

[215] P-00432 (01/19/2009 memo from Hazewski, Krueztner and Tomkiewicz to Zimmerman re. RVP Talking Points) .

thresholds will be changed unless there is a change in the customer's ratio of CS."[216]

154. Mr. Perry had been trained that a high controlled substance ratio could be a concern and was a question on the 590 form.[217] Mr. Perry admitted that at the time the threshold was adjusted, Regulatory Affairs knew the controlled substance ratio was high, that more than one distributor was being used, and that the pharmacy was filling prescriptions for pain clinics.[218]

155. When Mr. Perry forwarded via email the Request for Threshold Review, he also forwarded an email from SafeScript, which noted "Troublesome Drugs" – oxycodone and oxycontin and identified three prescribers including doctors Deleno Webb and Philip Fisher.[219] Mr. Perry testified that he had no knowledge regarding any issues with Dr. Webb.[220] He testified that he provided the names because they had asked for the information but he had no idea what Regulatory Affairs did with the names.[221] He did not know that Dr. Webb was a psychiatrist.[222]

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[216] *Id*..

[217] 5/19/21 Trial Tr (Perry) at 98.

[218] 5/19/21 Trial Tr. (Perry) at 140-145.

[219] P-16651 (7/29/2011 email from Perry to Hazewski re: Threshold Limits at Safescript Rx); 5/19/21 Trial Tr. (Perry) at 131. In 2005, Dr. Webb was banned by the West Virginia Worker's Compensation Commission from receiving payment for treating injured workers and surrendered his medical license in 2017. 6/15/21 Trial Tr. (Keller) at 181-182. Dr. Fisher's license to practice osteopathic medicine was suspended in 2011 and was the subject of a number of board actions pertaining to his prescribing practices as relating to the deaths of at least seven patients. 6/15/21 Trial Tr. (Keller) at 134.

[220] 5/19/21 Trial Tr. (Perry) at 131.

[221] 5/19/21 Trial Tr. (Perry) at 133.

[222] 5/19/21 Trial Tr. (Perry) at 142; 6/15/21 Trial Tr. (Keller) at 133 (Dr. Webb was also a pain management doctor).

156. SafeScript was raided by the police and closed in February 2012, approximately six months after ABDC increased its threshold levels to the maximum.[223] Mr. Perry was unaware of anyone from Regulatory Affairs ever visiting SafeScript from 2004 until its closure in 2012.[224]

157. In total, from July 2007 until July 2011, ABDC's Order Monitoring Program ("OMP") lagged at least 1,171 SafeScript orders for exceeding thresholds, including 775 orders of opioids. [225] However, ABDC only reported 41 SafeScript orders to the DEA as suspicious, including just 16 opioid orders.[226] Although ABDC internally flagged 617 SafeScript orders of oxycodone as suspicious, it only reported 13 orders to the DEA, on just 3 days: March 28, 2008, December 31, 2009, and January 30, 2010.[227]

158. SafeScript was not the only local pharmacy for which ABDC failed to conduct due diligence. In 2015, the DEA conducted an audit of the ABDC Lockbourne distribution center that serves Cabell and Huntington.[228] During the audit, the DEA diversion investigator requested copies of the due diligence files for several customers, including McCloud and Drug Emporium.[229] ABDC could not locate the files as the McCloud "Lawtrac matter is empty" and "requesting hard file from Iron Mountain – file not found."[230] Similarly, ABDC found that the Drug Emporium

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[223] 5/19/21 Trial Tr. (Perry) at 145.

[224] 5/19/21 Trial Tr. (Perry) at 129-130.

[225] P-16639a (2008-2011 ABDC Reported Orders to DEA from WV).

[226] P-44766 (2007-2011 ABDC Reported Orders to DEA from WV).

[227] P-16639a (2008-2011 ABDC Reported Orders to DEA from WV)..

[228] P-17140 (9/29/2015 email from Cherveny to May re: Columbus DEA Audit Update (9/29/15)); 5/17/21 Trial Tr. (May) at 167:1-169:10.

[229] *Id.; see also* 5/17/21 Trial Tr. (May) at 169:11-19.

[230] *Id.; see also* 5/17/21 Trial Tr. (May) at 170:14-19. Lawtrac was ABDC's electronic databased which contained its customer's due diligence information prior to its current iteration known as Archer. 5/17/21 Trial Tr. (May) at 166. Iron Mountain is where ABDC stores its hard copy documents. 5/17/21 Trial Tr. (May) at 174-175.

"Lawtrac matter is empty."[231] This strongly suggests that there were no files to be found.

2. ABDC's Notice of its OMP and Anti-Diversion Program Deficiencies

a. The DEA did not Approve ABDC's Diversion Control Program.

159. The DEA does not approve or endorse SOM systems.[232] Former Deputy Administrator for DEA's Office of Diversion Control, Mr. Rannazzisi,[233] testified that a DEA inspection does not enable DEA to determine a SOM system's effectiveness.[234] He further testified that the DEA did not have a SOM approval process and, in fact, communicated the fact that it did not approve SOM programs for registrants.[235] Mr. Rannazzisi explained that the reason it is the registrant's obligation to design and operate a system (rather than the DEA) is because:

> only the registrant knows or can develop a system that conforms to their business plan, to their customer base. DEA can't do that. DEA doesn't know what their customer base is. Doesn't know what their business plan is. Doesn't know how they process orders. Only the registrant could do that.[236]

160. Further, in 2007, the DEA advised counsel for ABDC that the Settlement and Release Agreement relating to the OSC/ISO[237] did "not approve or endorse a particular system to identify and disclose suspicious orders."[238]

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[231] P-17140 (9/29/2015 email from Cherveny to May re: Columbus DEA Audit Update (9/29/15)); 5/17/21 Trial Tr. (May) at 171:6-8.

[232] Prevoznik, 4/18/19 Depo at 752.

[233] 6/7/21 Trial Tr. (Rannazzisi) at 162, 165.

[234] 6/8/21 Trial Tr. (Rannazzisi) at 178-79.

[235] 6/8/21 Trial Tr. (Rannazzisi) at 182; *see also* 6/9/21 Trial Tr. (Rannazzisi) at 76 (has seen no document that would lead defendants to believe DEA approved their SOM systems before 2005); 220 (DEA did not approve SOM programs during or before tenure); 238 (told in 2005 that DEA not approve SOMs).

[236] 6/10/21 Trial Tr. (Rannazzisi) at 73.

[237] FOF, *infra*, ¶¶ 164-65.

[238] P-00521; 5/13/21 Trial Tr. (Zimmerman) at 217-218.

b. The 2000 Memorandum of Understanding

161. As far back as 2000, ABDC received direct communications from the DEA that indicated ABDC's SOM system did not adequately provide effective controls to prevent diversion. Specifically, in 2000, the DEA and ABDC entered into a Memorandum of Understanding, which alleged ABDC's failure to "provide effective controls and procedures to guard against theft and diversion of controlled substances required by 21 CFR 1301.71(a)" at the Columbus Lockbourne facility which services Cabell and Huntington.[239]

c. The 2005 Distributor Initiative Meeting

162. On August 10, 2005, the DEA held a "Distributor Initiative Meeting" with ABDC.[240] During this meeting, the DEA communicated to ABDC that it had a duty to report suspicious orders when discovered.[241] The DEA also advised ABDC that "reporting a suspicious order to DEA does not relieve a distribution [sic] of the responsibility to maintain effective controls."[242] The DEA wanted to make sure that ABDC understood what their obligations were and to make appropriate corrections to the system ABDC was operating.[243] Mr. Rannazzisi testified:

> The reason for the distributor initiative meetings was because we weren't getting suspicious orders. We weren't getting the suspicious orders that basically pinpointed or was a pointer system to potential diverters. What we were getting was excessive purchase reports and, and the like of the excessive purchase reports which are not suspicious orders.[244]

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[239] P-00324_00001; Cherveny, 11/9/18 Depo. at 262-67.

[240] 6/8/21 Trial Tr. (Rannazzisi) at 60.

[241] P-09112 at 9 (08/16/2005 Memo from Mapes to Walker re: Internet Presentation with AmerisourceBergen on August 10, 2005); 5/12/21 Trial Tr. (Zimmerman) at 199-200.

[242] P-09112 at 9 (08/16/2005 Memo from Mapes to Walker re: Internet Presentation with AmerisourceBergen on August 10, 2005); 5/12/21 Trial Tr. (Zimmerman) at 202.

[243] 6/8/21 Trial Tr. (Rannazzisi) at 63.

[244] 6/8/21 Trial Tr. (Rannazzisi) at 103.

163. Mr. Rannazzisi's testimony is bolstered by Michael Mapes, former DEA Section Chief for E-commerce, who also testified that the DEA was "looking for reports that the wholesalers had reviewed, not just with a raw number of drugs that were ordered but reviewed it and determined that it was suspicious."[245] Mr. Mapes further testified that he did not recall the DEA making a distinction between retail chain pharmacies and independent pharmacies during the distributor briefings.[246] He also testified that he "was expecting that over time they would use the same procedures for all the pharmacies that they were dealing with to be certain that there wasn't a problem that they wouldn't see without the extra due diligence."[247] He testified that the distributors were to be looking for "an internet pharmacy or any pharmacy that was selling drugs for other than legitimate purpose" such as a pill mill.[248] During the meeting, the DEA provided Steve Mays a binder full of written materials, which included a PowerPoint presentation, and case law regarding a distributor's general obligations to maintain effective controls to prevent diversion.[249]

d. The 2007 Order to Show Cause and Immediate Suspension Order

164. The DEA filed an Order to Show Cause and Immediate Suspension Order ("OSC/ISO") against ABDC on April 19, 2007.[250] The OSC/ISO immediately stripped ABDC's

[245] Mapes, 7/11/2019 Depo. at 202-203.

[246] Mapes, 7/11/2019 Depo. at 217.

[247] Mapes, 7/11/2019 Depo. at 217.

[248] Mapes, 7/11/2019 Depo. at 217.

[249] 5/17/21 Trial Tr. (May) at 179-181; *see also* P-08813 (08/10/2005 Internet Pharmacy Data Meeting with ABDC).

[250] 6/8/21 Trial Tr. (Rannazzisi) at 58-59; P-00049 (Apr. 2007 DEA Order to Show Cause and Immediate Suspension of Registration to ABDC).

Orlando, Florida facility of its license to distribute controlled substances.[251] The OSC/ISO identified the conduct that the DEA believed violated the CSA to include "notwithstanding the information provided to respondent after the August 10, 2005 meeting . . . Respondent sold over 5.2 million dosage units of hydrocodone to pharmacies that bore the characteristics that DEA described in the August 10th meeting." [252] In 2005 and 2006, ABDC continued to distribute massive volumes of hydrocodone to internet pharmacies in Florida, despite the warnings provided to it by the DEA via the distributor's initiative meetings and the September 2006 "Dear Registrant" letter.[253]

165. Mr. Rannazzisi testified that the failures of ABDC's systems that lead to the OSC and ISO were a total breakdown throughout ABDC's national SOMs program.[254] The conduct at issue included allowing the diversion of hundreds of thousands of dosage units into the illicit market.[255] The pills ordered from the internet pharmacies went all over the country and were not geographically limited.[256] By their nature, internet pharmacies, which shipped opioids to any location, would have provided opioids across the United States, including West Virginia.[257]

[251] P-00049 (Apr. 2007 DEA Order to Show Cause and Immediate Suspension of Registration to ABDC).

[252] 6/8/21 Trial Tr. (Rannazzisi) at 60-61; P-00049 at 3 (Apr. 2007 DEA Order to Show Cause and Immediate Suspension of Registration to ABDC).

[253] P-00049 (Apr. 2007 DEA Order to Show Cause and Immediate Suspension of Registration to ABDC)..

[254] 6/8/21 Trial Tr. (Rannazzisi) at 67.

[255] 6/8/21 Trial Tr. (Rannazzisi) at 70-72.

[256] 6/7/21 Trial Tr. (Rannazzisi) at 191-92.

[257] 6/7/21 Trial Tr. (Rannazzisi) at 169 (internet trafficking was taking over a lot of the pharmaceutical issues and diversion that was happening in the United States across the country).

166. The DEA and ABDC entered into a Settlement and Release Agreement on June 22, 2007 ("Settlement Agreement") in relation to the conduct alleged in the OSC/ISO.[258] The "covered conduct" in the Settlement included:

> The alleged failure of AmerisourceBergen to maintain adequate controls against diversion of controlled substances, on or prior to May 22nd 2007, at the Orlando facility and *all other distribution facilities* controlled by AmerisourceBergen, with respect to all sales of Automation of Reports and Consolidated Orders System reportable controlled substances, benzodiazepines and phentermine; and, three, the alleged failure to detect and report suspicious orders of sales of the controlled substances set forth in Subsection I(3)(ii) of this agreement as required by 21, C.F.R., 1301.74(b).[259]

167. The controlled substances mentioned in the settlement included opioids.[260] The Settlement Agreement covered all distribution centers including the Lockbourne, Ohio location that shipped opioids to Cabell and Huntington.[261] As a result, ABDC finally agreed to maintain a compliance program to detect and prevent diversion of controlled substances.[262] Mr. Rannazzisi further testified that while the DEA did not initiate additional enforcement actions against ABDC, that "doesn't mean they were compliant."[263]

e. <u>The FTI Consulting, Inc. Report</u>

168. In 2014, seven years into the OMP, ABDC retained FTI Consulting, Inc. ("FTI") to assist the company with an assessment of its CSRA department in identifying critical gaps or

[258] 6/8/21 Trial Tr. (Rannazzisi) at 68; P-00009 (June 2007 DEA-ABDC Settlement Agreement).

[259] 6/8/21 Trial Tr. (Rannazzisi) at 68-69; P-00009 at 2 (emphasis added) (June 2007 DEA-ABDC Settlement Agreement).

[260] 6/8/21 Trial Tr. (Rannazzisi) at 69.

[261] 5/12/21 Trial Tr. (Zimmerman) at 226-227.

[262] 5/12/21 Trial Tr. (Zimmerman) at 227-28.

[263] 6/8/21 Trial Tr. (Rannazzisi) at 72.

areas for improvement.[264] FTI's investigation found numerous systemic issues with the staffing, roles, training, and direction provided for its compliance efforts.[265]

169. The systemic issues FTI found included *inter alia*, "ill-defined" roles which resulted in CSRA team members performing activities outside their purview, inadequate training and insufficient staffing with necessary resources or expertise, personnel overwhelmed by the volume of activities and demands of their position and lack of direction; compliance activities not occurring because responsibilities are unclear, perpetual state of reacting impeding ability to implement and sustain organization improvements; and the lack of a policy regarding which associate(s) at the distribution center are responsible for reviewing orders.[266] FTI also found ABDC failed to provide guidance or "visibility to the process and rationale for adjudicating orders held for review" and noted there is no standard set of defined reasons to support those decisions" regarding holding orders.[267]

f. Notice Among ABDC's Anti-Diversion Team

170. The members of ABDC's diversion control team have been aware for decades of the risk of opioid addiction, the emerging opioid epidemic, and the relationship between pain pills and heroin. ABDC has admitted to long-held knowledge of the following:

- Based on information from the DEA, oxycontin "was a high risk for potential diversion" and necessitated closer scrutiny; [268]

[264] 5/14/21 Trial Tr. (May) at 53:18-64:14, 67:20-25; P-00093 at 7 (FTI Consulting ABDC CSRA Process Review – Phase 1 Narrative Report).

[265] P-00093 (FTI Consulting ABDC CSRA Process Review – Phase 1 Narrative Report). .

[266] *Id.* at 7-14.

[267] P-00472 (9/2/2015 email from Duncan to Gundy, Mays, May, Zimmerman, and Ross re: Matter Management: Final Review of Phase 1 FTI Findings & Recommendations, updated with team feedback).

[268] Hazewski, 10/25/18 Depo at 61-62.

- "The public health dangers associated with the diversion and abuse of controlled prescription drugs[,]" which "have been well-recognized over the years by Congress, DEA, HDMA, its members, and public health authorities.";[269]

- Oxycontin and hydrocodone have been viewed as high-risk drugs based in part upon ABDC's monitoring of drug abuse trends ("*We also, of course, monitor to the extent that we can abuse trends, drug abuse trends.*") from information in public sources and obtained from federal and state regulators;[270]

- Interstate diversion occurring from Florida, the Blue Highway and the Oxy Express,[271] including through mail parodies regarding "Pillbillies" and "Oxycontinville,"[272] which suggest a well-established and widespread recognition of diversion and abuse of prescription opioids in West Virginia, Appalachia, and elsewhere;

- Huge quantities of hydrocodone being purchased from illegal online pharmacies in Appalachia region;[273]

- Opioids being diverted and sold on the black market;[274] and that

- There is an opioid epidemic in this country and in Cabell and Huntington.[275]

171. In 2007, ABDC's Senior Vice President of Corporate Security & Regulatory Affairs, Chris Zimmerman, forwarded an article regarding rogue online pharmacies that were

[269] 5/13/21 Trial Tr. (Zimmerman) at 135.

[270] 5/14/21 Trial Tr. (May) at 57-58.

[271] Hazewski, 10/25/18 Depo at 71-72 (Pill migration from Florida to West Virginia, Ohio and other states was "generally discussed information in the industry" and a red flag for diversion because a person with legitimate medical need would not travel out of state); *see also* 5/13/21 Trial Tr. (Zimmerman) at 84-90, 96-99 (ABDC Pillbillies emails; knowledge of heroin connection, knowledge of interstate diversion from Florida); *see also* Mash, 7/28/20 Depo at 81-82, 118 (discussed OxyExpress, diversion from Fla. through WV, during training to be ABDC VP of Sales in WV; cluster of out-of-state license plates at pharmacy store was red flag for sales people).

[272] P-00212 (4/22/2011 email from Eddy to Zimmerman re: Saw This and Had to Share it…..); P-00217 (4/22/2011 email from Eddy to Zimmerman re: Saw This and Had to Share it…..); 5/13/21 Trial Tr. (Zimmerman) at 84-90, 96-99.

[273] 5/13/21 Trial Tr. (Zimmerman) at 93.

[274] P-17051 (8/23/2007 email from Zimmerman to Bray, Shook, Ross, Hazewski, Kirsch, and others re: FYI – Article on Rogue Pharmacies).

[275] 5/13/21 Trial Tr. (Zimmerman) at 214; 5/19/21 Trial Tr. (Perry) at 200.

illegally dispensing hydrocodone and other prescription drugs, and acknowledged the issues of opioid abuse and diversion in Appalachia, writing, "Not only is this part of the country purchasing the majority of the hydrocodone from legitimate pharmacies, but they also buy a huge quantity from illegal on line [sic] pharmacies. There is a whole lot of pain in the Appalachia area."[276]

172. Mr. Zimmerman admitted that the Beverly Hillbillies parody that he forwarded in 2011 included an implicit recognition that there was pill migration from Florida up into Mountaineer land.[277] He was aware of the term "pillbillies" being used to describe "people that go down and pick up the drugs and then resell them."[278] In fact, he used the term himself when forwarding an email about Florida enacting opioid reforms stating, "Watch out Georgia and Alabama. There will be a mass exodus of pillbillies heading north."[279]

3. ABDC'S Opioid Distribution into Cabell and Huntington

173. The evidence also demonstrates that ABDC has shipped vast quantities of opioid dosage units to Cabell County and Huntington pharmacies that are far in excess of its per capita shipments both nationally and even elsewhere in West Virginia, where ABDC's per capita opioid shipments also have been far above its national shipments.

174. Between June 2002 and December 2018, ABDC distributed 36 million dosage units of hydrocodone and oxycodone to retail pharmacies in Cabell and Huntington, a community of

[276] P-17051 (8/23/2007 email from Zimmerman to Bray, Shook, Ross, Hazewski, Kirsch, and others re: FYI – Article on Rogue Pharmacies).; 5/13/21 Trial Tr. (Zimmerman) at 93.

[277] 5/13/21 Trial Tr. (Zimmerman) at 86- 90; P-17046.

[278] 5/13/21 Trial Tr (Zimmerman) at 90.

[279] P-00282 (5/6/2011 email from Zimmerman to Eddy, Norton, Mays, Ross, Reid Brecko, and Short re: Agreement for FL pill mill reached and will pass (HB 7095)); 5/13/21 Trial Tr (Zimmerman) at 95-96.

100,000 people.[280] Between 2006 and 2014, ABDC's monthly average shipments of oxycodone to Cabell and Huntington pharmacies was 10,743 dosage units compared to its national average of 5,036 units.[281] In January 2006, ABDC's hydrocodone shipments to West Virginia doubled the national per pharmacy average.[282] From 2005 to 2016, ABDC shipped 248.16 million dosage units of oxycontin and hydrocodone to West Virginia.[283] From 2007 through 2018, there were 77,398 transactions by ABDC with pharmacies in Huntington-Cabell County, West Virginia.[284]

175. In January 2006, the national average shipments from ABDC of oxycodone to retail pharmacies was 3,424; to West Virginia it was 4,764; and to Cabell and Huntington it was 7,569 – 220% of the national average.[285] In January 2010, the national average shipments of ABDC of oxycodone to retail pharmacies was 4,683 units; to West Virginia was 6,849 units; and to Cabell and Huntington it was 15,186 units – 3.5 times the national average.[286]

176. During January 2006, the national average sales of oxycodone were 3,424 a month.[287] During that same month, ABDC shipped 38,100 dosage units to SafeScript #6.[288] The national average in November 2006 was 3,649 and the amount shipped to SafeScript #6 was

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[280] P-44711_00021 (2006-2018 Opioid Shipments to Cabell County); *see also* 5/18/21 Trial Tr. (Mays) at 115-117.

[281] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County); 5/10/21 Trial Tr. (McCann) at 115-116.

[282] 5/18/21 Trial Tr. (Mays) at 117-118.

[283] Prevoznik, 5/17/19 30(b)(6) Dep. (DEA) at 967-68.

[284] 5/26/21 Trial Tr. (Rafalski) at 103.

[285] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County); 5/10/21 Trial Tr. (McCann) at 117-118.

[286] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County). ; 5/10/21 Trial Tr. (McCann) at 116-117, 118.

[287]P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County); 5/18/21 Trial Tr. (Mays) at 121.

[288] *Id.*

56,700.[289] Steve Mays admitted that the amounts shipped to SafeScript were clearly in excess of the national average.[290]

177. The average shipment of oxycodone to SafeScript by ABDC from 2006 to 2012 was 35,551 – 600% more than the national average.[291] This would amount to 426,000 dosage units of oxycodone a year to SafeScript from ABDC compared to ABDC's national average of 60,000.[292] Between January 2006 and February 2012, ABDC sold and shipped 2,630,740 oxycodone dosage units to SafeScript in Cabell and Huntington.[293]

178. Between January 2006 and December 2014, the average oxycodone shipment from ABDC to McCloud Family Pharmacy was 18,028 – 260% higher than the national average.[294] The shipments of oxycodone from ABDC to McCloud Family Pharmacy steadily increased from 4,300 in January 2006 to 24,500 in January 2010.[295] In March of 2011, the shipments from ABDC to McCloud Family Pharmacy reached 39,900.[296] Between January 2006 and December 2014, ABDC sold and shipped 1,946,980 oxycodone dosage units to McCloud Family Pharmacy in Cabell and Huntington.[297]

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[289] *Id.*

[290] *Id.; see also* 5/18/21 Trial Tr. (Mays) at 122.

[291] *Id.; see also* 5/10/21 Trial Tr. (McCann) at 119.

[292] *Id.; see also* 5/10/21 Trial Tr. (McCann) at 119-120.

[293] *Id.*

[294] *Id.; see also* 5/10/21 Trial Tr. (McCann) at 120.

[295] *Id.*

[296] *Id.*

[297] *Id.*

179. Drug Emporium #1 is located in Barboursville in Cabell County. Barboursville had a 2010 population of 3,964.[298] Between January 2006 and December 2014, the average oxycodone shipment from ABDC to Drug Emporium was 13,505 dosage units.[299] The shipments of oxycodone from ABDC to Drug Emporium increased from 7,100 in January 2006 to 17,100 in January 2010.[300] In March 2010, the shipments from ABDC to Drug Emporium reached 24,500.[301] Between January 2006 and December 2014, ABDC sold and shipped 1,458,500 oxycodone dosage units to Drug Emporium in Cabell and Huntington.[302] By December 2009, ABDC had set Drug Emporium #1's thresholds for both drugs at about double the order volumes that had raised suspicions in 2007: 55,440 per month for hydrocodone and 40,000 per month for benzodiazepine.[303]

180. Between January 2006 and May 2012, the average oxycodone shipment from ABDC to Medical Park Pharmacy was 14,807 dosage units.[304] The shipments of oxycodone from ABDC to Medical Park Pharmacy increased from 2,000 in January 2006 to 19,900 in January 2010.[305] In March 2010, the shipments from ABDC to Medical Park Pharmacy reached 25,700.[306]

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[298] ECF No. 1433-7.

[299] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County); 5/10/21 Trial Tr. (McCann) at 121.

[300] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) .

[301] *Id*.

[302] *Id*.

[303] P-44766 (2007-2011 ABDC Reported Orders to DEA from WV).

[304] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) ; 5/10/21 Trial Tr. (McCann) at 121.

[305] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) .

[306] *Id*.

Between January 2006 and May 2012, ABDC sold and shipped 1,140,160 oxycodone dosage units to Medical Park Pharmacy in Cabell and Huntington.[307]

181. Between January 2006 and December 2009, the average oxycodone shipment from ABDC to Fruth Pharmacy #5 was 11,525 dosage units.[308] The shipments of oxycodone from ABDC to Fruth # 5 increased from 8,600 in January 2006 to 10,200 in December 2006.[309] In December 2008, the shipments from ABDC to Fruth #5 reached 17,400.[310] Between January 2006 and December 2009, ABDC sold and shipped 553,200 oxycodone dosage units to Fruth #5 in Cabell and Huntington.[311]

182. Between January 2006 and December 2014, the average oxycodone shipment from ABDC to Fruth #12 was 10,363 dosage units.[312] The shipments of oxycodone from ABDC to Fruth #12 increased from 10,400 in January 2006 to 12,300 in December 2009.[313] In April 2008, the shipments from ABDC to Fruth #12 reached 16,400.[314] Between January 2006 and December 2009, ABDC sold and shipped 497,400 oxycodone dosage units to Fruth #12 in Cabell and Huntington.[315]

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[307] *Id*.

[308] P- *Id.; see also* 5/10/21 Trial Tr. (McCann) at 121.

[309] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County).

[310] *Id*.

[311] *Id.*

[312] *Id.; see also* 5/10/21 Trial Tr. (McCann) at 121.

[313] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) .

[314] *Id.*

[315] *Id*.

183. Between January 2006 and December 2014, the average oxycodone shipment from ABDC to Fruth #2 was 7,256 dosage units.[316] The shipments of oxycodone from ABDC to Fruth #2 increased from 4,700 in January 2006 to 12,200 in December 2009.[317] Between January 2006 and December 2009, ABDC sold and shipped 348,300 oxycodone dosage units to Fruth #2 in Cabell and Huntington.[318]

184. Between January 2006 and December 2014, the average oxycodone shipment from ABDC to Fruth #11 was 4,915 dosage units.[319] Between January 2006 and December 2009, ABDC sold and shipped 235,900 oxycodone dosage units to Fruth #11 in Cabell and Huntington.[320]

185. Between April 2013 and December 2014, the average oxycodone shipment from ABDC to Walgreens #11977 was 11,205 dosage units.[321] The shipments of oxycodone from ABDC to Walgreens #11977 increased from 4,100 in April 2013 to 15,300 in December 2014.[322] During that same time period, ABDC sold and shipped 235,300 oxycodone dosage units to Walgreens # 11977.[323]

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[316] *Id.; see also* 5/10/21 Trial Tr. (McCann) at 121.

[317] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) .

[318] *Id.*

[319] *Id.; see also* 5/10/21 Trial Tr. (McCann) at 121.

[320] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) .

[321] *Id; see also* 5/10/21 Trial Tr. (McCann) at 121.

[322] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) .

[323] *Id*.

186. The average monthly oxycodone purchases from ABDC by its customers SafeScript, McCloud Family Pharmacy, Drug Emporium, Medical Park Pharmacy, the four Fruth Pharmacies, and Walgreens, is in excess of 100,000 oxycodone pills every month in Cabell-Huntington pharmacies.[324] The numbers for ABDC's sales of hydrocodone to the local Cabell and Huntington pharmacies follow a similar magnitude both in gross numbers and compared to the national average.[325]

187. Based on the forgoing, the Court finds that ABDC failed to maintain adequate or effective controls to prevent diversion of prescription opioids into the illicit market in Cabell and Huntington. ABDC failed to design and operate an effective system to identify, block, and report suspicious orders of opioids from pharmacies in Cabell and Huntington. ABDC did not conduct sufficient due diligence in general and specifically as it relates to investigations of the orders ABDC itself flagged as suspicious. ABDC's failures were systemic and were a substantial factor in the diversion of prescription opioids into the illicit market in Cabell and Huntington.

C. Cardinal

188. Cardinal Health has a nationwide distribution model and nationwide policies governing compliance with the CSA, and those policies were to be implemented uniformly across the country. [326]

189. Cardinal Health is a wholesale distributor of pharmaceutical medications, including prescription opioids. Known as one of the "Big 3" distributors in the United States along with AmerisourceBergen and McKesson, Cardinal operates around two-dozen distribution centers

[324] *Id.*; see also 5/18/21 Trial Tr. (Mays) at 123.

[325] *Id.*.

[326] 5/20/21 Trial Tr. (Moné) at 53.

throughout the country.[327] From its Wheeling, West Virginia distribution center, Cardinal distributed more than 17,687,705 dosage units of oxycodone and 19,590,250 dosage units of hydrocodone into Huntington/Cabell County, West Virginia from 1996 to May 2018.[328]

190. Despite growing evidence of the opioid epidemic in West Virginia, Cardinal reported minimal suspicious orders in Cabell County. Excluding suspicious orders Cardinal attempted to report through its Ingredient Limit Reports, which were reported only after the orders had already shipped, from 1996 through 2011, Cardinal reported *only one suspicious order* out of 92,915 transactions with pharmacies in in Cabell and Huntington.[329]

191. Cardinal has admitted that the purpose of its duties under the C.S.A. was to report and stop shipment of suspicious orders to prevent diversion.[330]

1. Cardinal's Suspicious Order Monitoring System

192. Cardinal has operated three different suspicious order monitoring systems from the late 1990's until the present day. The first operated from the late 1990's to 2008, the second from 2008 to 2012, and the third from 2012 to present. While there were changes to each system over time, the systems were generally the same in that they all utilized a monthly volume-based threshold trigger for identifying suspicious orders. As set out in more detail below, under each system when the number of pills ordered by a particular pharmacy exceeded a predetermined threshold in a given month it caused a triggering event. This trigger was a type of "alarm" that would indicate to Cardinal that a pharmacy placed an order of unusual size for that pharmacy.

[327] 5/20/21 Trial Tr. (Moné) at 167; Reardon, 532:4-532:17.

[328] P-44711_00024 (2006-2018 Opioid Shipments to Cabell County).

[329] *See* 5/26/21 Trial Tr. (Rafalski) at 104-05.

[330] *See* Reardon, 11/30/18 Depo. at 420-21.

a. Cardinal's SOMs late 1990's to 2008

193. From the late 1990's until 2008, Cardinal's SOMs was based on a dual system: (1) monthly Ingredient Limit Reports (ILRs) generated for each distribution center and (2) distribution center employees' daily observation of individual orders to identify suspicious orders.[331] Both of these were facially insufficient and failed in practice to comply with the CSA's requirements.

194. Each of Cardinal Health's distribution centers separately submitted ILRs in hard copies to the DEA each month that identified Cardinal customers whose total monthly purchases of schedules II-V drugs exceeded a predetermined limit.[332] The ILRs used thresholds based on the average amount in grams of each drug base code purchased by each class of customers (retail pharmacies, hospitals/managed care, and other) of each respective distribution center.[333] For opioids sold to retail customers, Cardinal multiplied that average by a factor of four to arrive at the limit for that month.[334] Each Cardinal distribution center generated its own report, and the system was the same across the country.[335]

195. Each ILR was hundreds of pages long and identified orders that Cardinal had determined were suspicious.[336] None of the orders identified in ILRs were reported to the DEA before they were shipped to Cardinal's customers, this system was after the fact reporting.[337]

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[331] P-14290 (Cardinal Health DEA Compliance Manual).

[332] *Id.; see also* P-14288 (Cardinal Compliance Group Ingredient Limit Report).

[333] The Chemical Handlers manual is designed to identify extraordinary orders of List I chemicals and is not applicable to controlled substances. 5/20 Trial Tr. (Moné) at 94-95.

[334] P-14288 (Cardinal Compliance Group Ingredient Limit Report) .

[335] 5/20/21 Trial Tr. (Moné) at 40-41.

[336] Reardon, 11/30/2018 Depo at 426-427.

[337] Reardon, 11/30/2018 Depo at 427-427.

196. The second part of this dual system was Cardinal's reliance on distribution center warehouse workers, referred to as "pickers and checkers", to identify excessive purchases on a daily basis. The pickers and checkers were supposed to manually flag orders that exceeded dosage limits set for specific drug formulations (morphine tablets versus liquid, for example). According to Cardinal's policy, the limits for opioids were set "by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customers and multiplying by 3."[338] The limits were posted in the cage or vault for pickers and checkers to compare with the orders they were preparing for shipment.[339]

197. According to Mr. Reardon, if an order exceeded these daily limits the pickers/checkers were to flag the order and there would be corresponding documentation related to each of these "excessive orders" in the respective pharmacy's due diligence file.[340] There is no evidence that Cardinal ever identified a single "excessive order" for any customer serviced by the Wheeling, West Virginia distribution center.[341]

198. There is also no indication in Cardinal's Standard Operating Procedures that there was any standardized process for investigating orders that were identified in the ILR or by the pickers and checkers.[342] Nor does there appear to have been any due diligence done on customers in response to an order flagged by distribution center pickers and checkers.[343]

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[338] P-14290_00147 (Cardinal Health DEA Compliance Manual).

[339] *Id.; see also* Reardon, 11/30/18 Depo. at 492-493; Brantley, 10/1/20 Depo at 533.

[340] *See* Reardon, 11/30/18 Depo. at 493-96.

[341] P-23655 (ABDC's 4th Supp. Objections and Responses to Plaintiffs' 1st Comb. Discovery Requests, Response to Request No. 3).

[342] P-14290_00144-00147, 00465-00470 (Cardinal Health DEA Compliance Manual) .

[343] P-23655 (ABDC's 4th Supp. Objections and Responses to Plaintiffs' 1st Comb. Discovery Requests, Response to Request No. 4).

199. It is clear that Cardinal's dual system considered the volume or size of orders, but there is no evidence that it considered the frequency or pattern of orders to its pharmacy customers that the governing regulations defined as suspicious.[344]

200. During this period, while Mr. Reardon oversaw Cardinal's Anti-Diversion Department, he was not aware of Cardinal's obligation under the CSA to maintain effective controls to prevent diversion. He was only aware of the regulation regarding the reporting of suspicious orders. He also acknowledged that Cardinal's ILR system and subsequent investigation were not sufficient to maintain effective controls against diversion.[345]

201. In 2005, Cardinal attended a meeting with the DEA in which the DEA provided specific guidance to Cardinal on its regulatory obligations and responsibilities to maintain effective controls against diversion.[346] During this meeting, the DEA communicated to Cardinal that it had a duty to report suspicious orders when discovered and that reporting those orders but shipping them anyway does not relieve Cardinal of the duty to maintain effective controls to prevent diversion.[347] The DEA also conveyed to Cardinal what had been recognized by the Supreme Court as early as 1943 – that drugs are inherently susceptible to harmful and illegal use.[348]

202. Cardinal received the DEA's first Rannazzisi letter in September 2006, and Cardinal, as well as its then-head of QRA Mr. Reardon, understood that the letter informed

[344] *See* 21 CFR 1301.74(b); 5/20 trial Tr. (Moné), at 75 (admitting Cardinal's thresholds were based on volume only).

[345] Reardon, 11/30/18 Depo at 416-418; 469-470; 453.

[346] *See* P-09114 (08/23/2005 Memo from Mapes to Rannazzisi re: Meeting with Cardinal Inc. Concerning Internet Pharmacies); 6/7/21 Trial Tr. (Rannazzisi) at 200.

[347] 6/7/21 Trial Tr. (Rannazzisi) at 213-15.

[348] P-09114_00004 (08/23/2005 Memo from Mapes to Rannazzisi re: Meeting with Cardinal Inc. Concerning Internet Pharmacies) .

Cardinal of a duty to stop shipment of suspicious orders.[349] Mr. Reardon testified that he understood the letter and would have asked DEA questions if he had not.[350] This suggests Cardinal was not surprised and already had an understanding by this time that shipping suspicious orders was not compliant with the Controlled Substances Act.[351]

203. Prior to 2008, Cardinal Health's QRA department operated without sufficient resources or personnel.[352] Only two to three people manually reviewed ILRs from the late 1990's to 2008.[353] The head of the QRA department at that time, Mr. Reardon, agreed three people was insufficient to properly investigate all of the suspicious orders that Cardinal's ILR system identified.[354] Michael Moné testified that when he took over the role of head of anti-diversion in December 2007, there were three people working in the department, which was insufficient.[355]

204. From August 2005 through December 2007, and in April 2008, Cardinal shipped suspicious orders of opioids to pharmacies in Cabell County that exceeded its ILR threshold amounts. The excess shipments from 259 invoiced orders contained 3,658.85 grams of opioids comprising 256,200 dosage units.[356] There is no evidence that Cardinal conducted due diligence on any of these suspicious orders prior to shipment.[357]

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[349] Reardon, 11/30/18 Depo. at 419:22-420:15; Norris, 10/2/20 Depo at 135:8-135:16.

[350] Reardon, 11/30/18 Depo. at 419:22-420:15.

[351] Norris, 10/2/20 Depo at 172:17-172:22.

[352] Lawrence, 10/1/2020 Depo at 200; 5/14/21 (Moné) Trial Tr. at 52; P-09734_0003

[353] Brantley, 10/1/2020 Depo at 150-151; 363.

[354] Reardon, 11/30/2018 Depo at 469-470.

[355] 5/19/21 Trial Tr. (Moné) at 205; 5/20 Trial Tr. (Moné) at 52; P-09734_0003.

[356] P-42432 (Aug. 2005-Dec. 2007 and Apr. 2008 Cardinal Suspicious order shipments to Cabell Co.).

[357] P-14288 (Cardinal Compliance Group Ingredient Limit Report) ; P-42432(Aug. 2005-Dec. 2007 and Apr. 2008 Cardinal Suspicious order shipments to Cabell Co.).

205. The following chart identifies the volume of suspicious order of opioids shipped to each pharmacy in excess of Cardinal's own limits from August 2005 through December 2007[358]:

Pharmacy	Opioids (Dosage Units/Pills)
KMART Pharmacy 5636 U.S. Route 60 E, Huntington, WV DEA #AK8905018	19,202
Med Associates Pharmacy, Inc., d/b/a Continuum Pharmacy, 78 Perry Winkle Lane, Huntington, WV DEA #BM6622167	66,031
Med Associates Pharmacy, Inc., dba Medical Associates #3 Chateau Lane, Barboursville, WV DEA #BM6647739	1,000
West Virginia CVS Pharmacy, LLC 505 Twentieth Street, Huntington, WV DEA #BR4301545	12,220
West Virginia CVS Pharmacy, LLC 2901 Fifth Ave., Huntington, WV DEA #BR4365486	71,036
T&J Enterprises, Inc., dba The Medicine Shoppe 2402 Adams Ave., Huntington, WV DEA #BT5541760	86,711

206. Many of the orders exceeded the applicable ingredient limits by large margins. For example, ten shipments to the Med Associates Pharmacy in Huntington were 1,000 to 20,000 dosage units above the relevant threshold.[359]

207. The Court agrees with Mr. Reardon's testimony that identifying and reporting suspicious orders after they have been shipped is not maintaining effective controls to prevent

[358] P-42432 (Aug. 2005-Dec. 2007 and Apr. 2008 Cardinal Suspicious order shipments to Cabell Co.).

[359] P-14288 (Cardinal Compliance Group Ingredient Limit Report) ; P-42432 (Aug. 2005-Dec. 2007 and Apr. 2008 Cardinal Suspicious order shipments to Cabell Co.).

diversion and not in compliance with the intent or the letter of the Controlled Substances Act. This system of Cardinal's was clearly deficient.

b. Cardinal's SOMs 2008 to 2012

208. After repeated discussion with the DEA related to Cardinal's SOMs, no changes were made until the DEA acted against Cardinal's licenses. On November 28, 2007, December 5, 2007, and December 7, 2007, the DEA served Orders to Show Cause and Immediate Suspension Orders on Cardinal's distribution centers in Auburn, Washington, Lakeland, Florida, and Swedesboro, New Jersey, respectively.[360] The DEA also served an Order to show Cause on Cardinal's Stafford, Texas distribution center on January 30, 2008.[361] The ISO's set out devastating facts related to the volume of pills being distributed by Cardinal out of each of these distribution centers across the country.

209. For example, the DEA alleged that Cardinal failed to maintain effective controls to prevent diversion at its Auburn distribution center after finding that Cardinal distributed more than 600,000 dosage units of hydrocodone to Horen's Drugstore from March 2007 through September 2007.[362] The DEA also alleged that from August 2005 to October 2007 Cardinal's Lakeland distribution center distributed more than 8,000,000 dosage units to customers it knew or should have known were diverting opioid pills.[363]

210. As a result of the DEA's orders to show cause and immediate suspension orders, in September 2008, Cardinal Health agreed to pay a $34 million civil penalty and enter an

[360] P-08873_00034 (1/25/2016 email from Giacalone to Callinicos re: DEA related documents and links).

[361] *Id*.

[362] *Id*. at 00051.

[363] *Id*. at 00055.

Administrative Memorandum of Agreement (MOA) with the DEA for its failure to maintain effective controls against diversion. The conduct covered by this MOA included "the alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances, on or prior to September 30, 2008 at all distribution facilities listed in Appendix A", which includes Cardinal's Wheeling, WV distribution center that serviced Cabell and Huntington, WV.[364] Cardinal Health failed to report or stop orders of large volumes of hydrocodone from certain pharmacies across the country.[365] As part of the agreement, Cardinal agreed "to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations."[366]

211. In response to these enforcement actions by the DEA, Cardinal began revamping their SOMs at the end of 2007 and beginning of 2008.[367] Cardinal's new SOMs was developed with the help of Michael Moné and utilized a threshold system. This system was designed to have a monthly trigger separately assigned to each customer, but this monthly trigger was set using a national average for the particular customer type (hospital, retail pharmacy, or long-term care provider) and then the customer size (small, medium, or large).[368] Once the national average for type and size was determined it was multiplied by a factor of three.[369] This meant that despite have specific knowledge of the existing opioid epidemic, Cardinal used opioid epidemic level numbers

[364] P-08873_00034-00036 (1/25/2016 email from Giacalone to Callinicos re: DEA related documents and links).

[365] 6/8/21 Trial Tr. (Rannazzisi) at 77-79

[366] P-08873_00036 (1/25/2016 email from Giacalone to Callinicos re: DEA related documents and links).

[367] 5/19/21 Trial Tr. (Moné) at 207-208.

[368] 5/20/21 Trial Tr. (Moné) at 59-60.

[369] *Id*.

to set thresholds for its customers.[370] Mr. Moné testified that Cardinal's policy to multiply these averages by a factor of three was based on the Chemical Handlers Manual, but admitted that the Manual was not intended for use with controlled substances unless they contain list one chemicals, which oxycodone and hydrocodone formulations generally do not.[371] Mr. Moné also agreed that the Chemical Handlers Manual by its own terms provides a system to identify "extraordinary orders" not "suspicious orders."[372]

212. This threshold system was designed to allow the threshold to be changed to fit the needs of each individual pharmacy customer.[373] However, in order to alter the pharmacy customer's threshold, Cardinal required that there be a legitimate business purpose for a threshold increase and specifically provided that the type of legitimate growth necessary would include a customer entering into a contract with a hospice, file purchase from another pharmacy, move into a medical center, or addition of a new cancer center.[374]

213. Cardinal's new SOMs also required significant onboarding investigations and continuous due diligence related to its customers, also referred to as the Know Your Customer (KYC) process.[375] This would entail the gathering of significant data from the potential pharmacy

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[370] 5/20/21 Trial Tr. (Moné) at 39-11; 60. Cardinal testified through its 30(b)(6) deposition designee that it was aware of the rising abuse of prescription drugs as early as 2006 when it received the first Rannazzisi letter. Norris, 10/2/20 Depo at 142-143. Cardinal's former head of QRA, Steve Reardon, also testified that he was aware of the opioid epidemic in 2007. Reardon, 11/30/18 Depo at 413-414.

[371] 5/20/21 Trial Tr. (Moné), 93-95.

[372] 5/20/21 Trial Tr. (Moné) at 95.

[373] P-01930_00064 (10/1/2008 email from Mone to Anderson re: Anti-Diversion CBT-Distribution Center Employees).

[374] P-01930_00075 (10/1/2008 email from Mone to Anderson re: Anti-Diversion CBT-Distribution Center Employees).

[375] 5/20/21 Trial Tr. (Moné) at 80-81, 97-98.

customer and then maintaining this process through due diligence during the time that Cardinal would be servicing the customer.[376] For example, Mr. Moné testified that any time there was a triggering event related to a threshold it essentially sounded an alarm for Cardinal to take action whether the customer exceeded the threshold, by a small amount or by a lot.[377] This is referred to as the due diligence process.[378]

214. Under this new system overseen by Mr. Moné, each pharmacy customer would have a threshold volume of pills for each drug base code[379] and if a customer exceeded that limit, even by a relatively small amount, the system would hold the order. The order would not be shipped until adequate due diligence was completed to dispel the suspicion of diversion surrounding the order. If the suspicion could be cleared based on the due diligence conducted, the order could be shipped. If the suspicion could not be cleared by conducting due diligence on the pharmacy customer, then the order remained blocked, the suspicious order was reported to DEA, the sales force for that customer would be notified, and the customer was to be terminated from purchasing controlled substances or in totality.[380]

215. According to its standard operating procedures for the post-2008 timeframe, Cardinal tasked its sales team with the responsibility to search for and identify signs of diversion or "Anti-Diversion alert signals," however, this policy was merely in writing and not widely

[376] 5/20/21 Trial Tr. (Moné) at 80-81.

[377] 5/20/21 Trial Tr. (Moné) at 61-62.

[378] 5/20/21 Trial Tr. (Moné) at 82.

[379] *E.g.*, the base code for oxycodone is 9143 and the base code for hydrocodone is 9193.

[380] P-14122_00121-122 (5/6/2008 email from Ramano to Mone re: Anti-Diversion and SOM Training).

adhered to among Cardinal's salespeople.[381] Cardinal's Senior Vice President of Independent Sales, to whom the sales force for non-chain pharmacies reported, testified that the sales force could not serve as the "front line of defense against…anything" because they are hired "right out of college" and their "real duty" was to sell Cardinal's distribution and marketing services to pharmacies, not to prevent diversion.[382]

216. Cardinal treated chain pharmacies much more favorably than it did independent pharmacies. For instance, Cardinal did not calculate thresholds for chain pharmacies in the same manner as other customers; it merely applied a standard threshold for the entire chain.[383] That meant that, regardless of a store's history of opioid orders, it would not trigger scrutiny if its volume suddenly or dramatically increased, so long as it was below the chain-wide threshold. Cardinal also failed to conduct its own due diligence on its chain pharmacy customers, and instead, relied on the chains to report this information. [384] Cardinal did not, however, make any effort to evaluate chain pharmacies' anti-diversion programs.[385]

217. From March 1, 2008, through August 31, 2009, Cardinal's SOMs was triggered 8,465 times for all shipments around the country. Of these, Cardinal only reported to the DEA 91 suspicious orders—roughly 1% of flagged orders; the balance of the orders was shipped.[386] In

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[381] P-14290_00782-00785 (Cardinal Health DEA Compliance Manual); 5/21/21 Trial Tr. (Kave) at 95.

[382] *See* Lawrence, 1/4/19 Depo at 35-37.

[383] P-00080_00015 (04/12/2013 Investigation Report of the Special Demand Committee – Board of Directors of Cardinal Health).

[384] P-00080_00020 (04/12/2013 Investigation Report of the Special Demand Committee – Board of Directors of Cardinal Health).

[385] 5/20/21 Trial Tr. (Moné) at 85.

[386] P-00077 (Feb. 2009 Cardinal Health SOM Program); P-07509 (6/5/2009 email from Rausch to Mone re: SOM Monthly Report

contrast, over a four-month period in 2012, Cardinal reported 113 suspicious orders for the Huntington Medicine Shoppe alone.[387]

218. When setting thresholds, Cardinal did not take into account objective measures, such as how a pharmacy's controlled substance purchases from Cardinal compared to national averages.[388] Plaintiffs' diversion investigation expert, James Rafalski, testified that there was no evidence in the record that Cardinal monitored the overall volume of hydrocodone and/or oxycodone each distributed into Cabell and Huntington County during the relevant time frames of the available data.[389]

219. Due to Cardinal's continued lack of compliance with its regulatory obligations, the DEA once again took action against Cardinal and on February 22, 2012, issuing another Order to Show Cause and Immediate Suspension Order on Cardinal's Lakeland, Florida distribution center. This ISO cited Cardinal's failure to conduct due diligence on its top four retail pharmacy customers, which included CVS 219 and CVS 5195 in Florida.[390] The DEA found that from January 1, 2008, through December 31, 2011, Cardinal shipped approximately 7.2 million dosage units to these two chain pharmacies.[391] Cardinal admitted that "its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were

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Attachment: Feb. 2009 Cardinal Health SOM Program); P-44267 (Aug. 2009 Cardinal Health SOM Program).

[387] P-42071 (Cardinal Health Flagged/Suspicious Orders).

[388] P-00080_00038 (04/12/2013 Investigation Report of the Special Demand Committee – Board of Directors of Cardinal Health).

[389] 5/26/21 Trial Tr. (Rafalski) at 58-59.

[390] P-08873 (1/25/2016 email from Giacalone to Callinicos re: DEA related documents and links).

[391] *Id*..

inadequate[.]"[392] Additionally, Cardinal admitted that between January 1, 2009 and May 14, 2012, Cardinal Lakeland failed to inform DEA that Certain orders for controlled substances it received from some customers were suspicious."[393] Significantly, Cardinal's centralized SOMs was national in scope and ran by Mr. Moné and his team in Dublin, Ohio.[394] It is clear from Mr. Moné's testimony that this system operated the same in Cabell County and Huntington, West Virginia as it did from Florida all the way to Seattle. Clearly, Cardinal's failures related to due diligence and reporting suspicious orders were systemic in nature and plagued the system as a whole.

c. Cardinal's SOMs 2012 to Present

220. After the 2012 DEA enforcement action Cardinal again revamped its system. Steve Morse, who Cardinal hired following the 2008 DEA action, was demoted for failing to timely terminate the pharmacies that were the subject of the 2012 action, despite finding evidence that ultimately led to the pharmacies' termination.[395] Morse was removed from his position as a Director of Investigations to a position in regulatory management.[396] Cardinal cited his questionable judgment as part of the reason for this demotion and the fact that Morse failed to review each pharmacy site visit report as required by Cardinal's 2008 SOP's.[397] As a result of the 2012 ISO and DEA investigation, Moné was moved from his position as Vice President of Anti-

[392] *See* 6/8/21 Trial Tr. (Rannazzisi) at 94-95.

[393] P-02037_0003 (Dec. 2016 DEA-Cardinal Settlement Agreement).

[394] 5/20/21 Trial Tr. at 39.

[395] P-00080_00035-00038 (04/12/2013 Investigation Report of the Special Demand Committee – Board of Directors of Cardinal Health).

[396] *Id*.

[397] *Id*.

Diversion into a position as an attorney with the company's regulatory group for his failures to terminate the pharmacies at issue in the ISO sooner.[398]

221. Cardinal's additional changes centered around the way that it was setting thresholds. Instead of using a national average multiplied by three, Cardinal began setting each pharmacy customers' thresholds based on prescription volume.[399] The basic premise was that if a Cardinal customer was filling more prescriptions, then that customer would have a corresponding need for higher thresholds. The other aspects of Cardinals system regarding KYC and due diligence remained unchanged.

222. Cardinal regularly permitted customers to exceed their thresholds for opioids. As a matter of policy customers that exceeded their threshold for a particular drug could receive a certain percentage of dosage units over the threshold once per month per drug family (*e.g.*, an additional 10% of oxycodone). Not surprisingly, Cardinal did not put this practice in their Standard Operating Procedures (SOP), but in a document called "General Work instructions."[400] This strongly suggests that Cardinal intended for these thresholds to create the appearance that it had a meaningful Suspicious Order Monitoring System, while the system in practice did very little to detect or prevent shipment of orders of unusual size, pattern, or frequency.

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[398] *Id.*

[399] *Id*.

[400] P-14290 (Cardinal Health DEA Compliance Manual).

2. Evidence of Cardinal's Due Diligence

223. Having reviewed the different systems maintained and operated by Cardinal during the relevant timeframe, the Court believes it significant to next review in detail what appears to be an important component of Cardinal's SOMs from 2008 to present as well as Mr. Rafalski's opinions about whether adequate due diligence was conducted by Cardinal on its customers in the onboarding process and when threshold were triggered.

224. Cardinal insists that it conducted adequate due diligence on all customers and in response to these triggering events.[401] The Court also recognizes that there was no written regulation requiring a registrant to maintain due diligence files for any particular period of time. However, Cardinal's own policies beginning in 2008 indicate that there should be customer files as part of the KYC program.[402] Cardinal has also indicated that its internal SOPS require these files be maintained for two years.[403]

225. Therefore, Cardinal should have complete due diligence files from on or about June 26, 2010, to present for all West Virginia customers and no later than March 9, 2015, to present specifically for its pharmacy customers in Cabell and Huntington.

226. This timeframe is based on Cardinal's representation that per the company's document retention policy, it maintained these files for a period of two years.[404] Therefore, Cardinal should have maintained complete due diligence files for these customers covering the timeframe from two years before these respective cases were filed to present.

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[401] 5/20/21 Trial Tr. (Moné) at 62-63.

[402] 5/20/21 Trial Tr. (Moné) at 172-174.

[403] 5/20/21 Trial Tr. (Moné) at 93.

[404] 5/20/21 Trial Tr. (Moné) at 93.

227. Cardinal does not have complete due diligence files for its Cabell and Huntington chain pharmacy customers. For example, there is no due diligence file for CVS 4419 or for CVS 10566.[405] Yet, Cardinal reported CVS 10566 to the DEA in July 2016 for a suspicious order of hydrocodone.[406] Based on the filing of the instant suit the due diligence surrounding the July 2016 suspicious order should exist and there is no evidence that it does. This is a failure on behalf of Cardinal to maintain adequate due diligence.

228. For CVS 3391, 4419, 4425, 3480, and 10566, CAH produced just 7 pages of due diligence.[407] There is no evidence that a due diligence file ever existed for K-Mart Pharmacy (AK8905018)[408] or ContinuumCare Pharmacy (FC1712668) in Huntington, both of which Cardinal reported to DEA for suspicious orders multiple times.[409] Cardinal reported 23 suspicious orders for opioids placed by K-Mart from June 2016 to October 2017.[410] Cardinal reported ContinuumCare Pharmacy three time from August 2015 to May 2016.[411]

229. In 2010 Cardinal acquired the chain of Fruth Pharmacy stores account from ABDC.[412] In the first six months of 2013, Cardinal reported 8 suspicious orders of hydrocodone

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[405] P-42071 (Cardinal Health Flagged/Suspicious Orders); P-23655 (ABDC's 4th Supp. Objections and Responses to Plaintiffs' 1st Comb. Discovery Requests).

[406] P-42071 (Cardinal Health Flagged/Suspicious Orders) .

[407] P-23655 (ABDC's 4th Supp. Objections and Responses to Plaintiffs' 1st Comb. Discovery Requests, Supp. Response to Request No. 4).

[408] While Cardinal produced documents related to its national corporate account with K-Mart, it has not produced or identified a due diligence file for its K-Mart Pharmacy customer in Cabell and Huntington.

[409] P-42071 (Cardinal Health Flagged/Suspicious Orders); P-23655 (ABDC's 4th Supp. Objections and Responses to Plaintiffs' 1st Comb. Discovery Requests, Supp. Response to Request No. 4).

[410] P-42071 (Cardinal Health Flagged/Suspicious Orders) .

[411] *Id*.

[412] 5/26/21 Trial Tr. (Rafalski) at 55-57.

placed by Fruth #5, but Fruth #5's due diligence file does not contain a single page of documentation from this timeframe.[413] In fact, the file lacks any documentation whatsoever from February 2010 to November 2013. There is no analysis of these suspicious orders or evidence of what Cardinal considered in evaluating these orders. Cardinal documents show that from December 2009 to June 2012 Cardinal raised Fruth Pharmacy #5's threshold for hydrocodone from 10,000 dosage units per month to 133,000 per month with absolutely no documented due diligence to justify a thirteen-fold increase in threshold .[414]

230. The Court next looks at Cardinal's customer known as T&J Enterprises, Inc. d/b/a Medicine Shoppe (hereafter, Medicine Shoppe) as it relates to the adequacy of due diligence conducted. Medicine Shoppe International, Inc., is a subdivision of Cardinal that franchises and services a network of pharmacies.[415] Cardinal distributes prescription opioids to Medicine Shoppe pharmacies, including T&J Enterprises, Inc., d/b/a The Medicine Shoppe, located in Huntington, West Virginia. Jesse Kave, the Cardinal salesperson assigned to the territory that included Cabell County, testified that Medicine Shoppe in Huntington was his biggest customer in the county.[416]

231. Cardinal reported no suspicious orders of opioids from Medicine Shoppe until 2010 and none for oxycodone until August 2012. Since then, Cardinal reported 66 suspicious orders of hydrocodone and 122 suspicious orders of oxycodone for Medicine Shoppe.[417]

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[413] P-42071 (Cardinal Health Flagged/Suspicious Orders); P-42100 (Fruth Pharmacy Anti-Diversion Customer Profile (2010-2014).

[414] P-44275 (lines 49 and 417) (Cardinal Health Reported Orders) ; P-42102.

[415] 5/20/21 Trial Tr. (Moné) at 203-204.

[416] 5/21/21 Trial Tr. (Kave) at 64; 77.

[417] P-42071 (Cardinal Health Flagged/Suspicious Orders).

232. From November 2012 to 2018, Cardinal reported 115 suspicious orders placed by Medicine Shoppe, but after November 2012 Cardinal's due diligence file for the pharmacy contains just 5 documents consisting of 18 pages.[418] From November 2010 to May 2011, Cardinal increased Medicine Shoppe's threshold for oxycodone repeatedly without any due diligence or justification associated with the threshold increases.[419] Cardinal repeatedly identified suspicious orders of opioids placed by Medicine Shoppe, shipped the orders and intentionally failed to report those orders to the DEA.[420] On February 9, 2012, Cardinal held an order placed by Medicine Shoppe for 8,000 dosage units of oxycodone because the order caused Medicine Shoppe to exceed its monthly threshold of 31,100 dosage units for oxycodone. The order was cut because, according to Cardinal Health, the "DATA [for Medicine Shoppe] DOES NOT SUPPORT QUANTITY ORDERED." The order was not reported to DEA, and QRA requested that an on-site investigation of Medicine Shoppe be conducted to determine the pharmacy's risk for diversion.[421]

233. In December 2011, Cardinal salesperson Jesse Kave notified QRA that he was informed by Medicine Shoppe's owner that he expected the pharmacy's purchases of *oxycodone to decrease due to changes in prescribing patterns*.[422] Four months later, on June 12, 2012, QRA pharmacist Doug Emma emailed senior Cardinal compliance officials Linden Barber and Gilberto

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[418] P-42116 (2008-2018 Cardinal Health Due Diligence File on Medicine Shoppe).

[419] P-44275 (*e.g.*, lines 249, 278, and 348) (Cardinal Health Reported Orders); P-42116 (2008-2018 Cardinal Health Due Diligence File on Medicine Shoppe).

[420] P-14294 (2012-2020 Cardinal Health Suspicious Orders Cabell County Pharmacies spreadsheet); P-42071 (Cardinal Health Flagged/Suspicious Orders) .

[421] P-14294 (2012-2020 Cardinal Health Suspicious Orders Cabell County Pharmacies spreadsheet, lines 62-66); P-42071 (Cardinal Health Flagged/Suspicious Orders); P-42116 (2008-2018 Cardinal Health Due Diligence File on Medicine Shoppe).

[422] P-42116_00063 (2008-2018 Cardinal Health Due Diligence File on Medicine Shoppe); 5/21 Trial Tr. (Kave) at 84-85.

Quintero regarding "suspected 'hot spots', black hole cases and cases that probably need to be revisited by LV-TAC." In that context, Emma advised that Medicine Shoppe "has seen a significant growth in both areas and to my knowledge a site visit has not been conducted after submitting 6 requests to validate growth[.]".[423]

234. In July 2012, Doug Emma noted in an email that he had "requested a site visit multiple time on [Medicine Shoppe]" and that QRA "still need[ed] to validate the business growth and increased utilization of pain medications. Later that month, another QRA pharmacist, Janet Ng, informed Cardinal Health's Michael Moné that "Doug Emma had requested multiple site visits since January."[424]

235. When a site visit was finally conducted for Medicine Shoppe on August 20, 2012, six months after the initial request, the investigation found that 1) 22% of prescriptions dispensed by the pharmacy were for controlled substances, which Cardinal considered "high", 2) 71% of oxycodone dispensed in the prior three months was for 15 and 30 mg formulations, a red flag according to Mr. Kave, and 3) that Cardinal saw a "disproportionate growth" of oxycodone purchases from Cardinal over the prior 12 months.[425] Eight months earlier in December 2011, Cardinal salesperson Jesse Kave notified QRA that he was informed by Medicine Shoppe's owner that he expected the pharmacy's purchase of oxycodone to decrease due to changes in prescribing patterns.[426] The site visit in August 2012 confirmed the opposite had happened.

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[423] P-28038 (6/12/2012 email from Emma to Baber and Quintero re: Follow-up to Training 6-5-2012).

[424] P-42116 (2008-2018 Cardinal Health Due Diligence File on Medicine Shoppe).

[425] CAH-WV-000770; 5/21/21 Trial Tr. (Kave) at 89-94.

[426] P-42116_00063 (2008-2018 Cardinal Health Due Diligence File on Medicine Shoppe) ; 5/21/21 Trial Tr. (Kave) at 84-85.

236. The August 2012 site visit also notes that Medicine Shoppe saw an increase in controlled substances dispensing due to the closing of another local pharmacy, Safescript.[427] The DEA shut down Safescript in a raid and arrested the owner.[428] The closing of Safescript coinciding with Medicine Shoppe dispensing an increasing volume of controlled substances illustrates the concept referred to by Cardinal Health as the "cockroach effect." In her 2012 performance evaluation, Kimberly Howenstein, who at that time was responsible for evaluating due diligence conducted on prospective customers for Cardinal[429], described this growth as the "cockroach effect" – closing a "bad" pharmacy often results in those customers "scatter[ing] to 'good' pharmacies."[430] From June to August 2012 alone, while requests for site visits went unanswered, Cardinal shipped at least 30 Medicine Shoppe orders for oxycodone or hydrocodone that it determined were suspicious but failed to report to the DEA.[431] Between 2013 and 2015, Cardinal identified at least twenty additional Medicine Shoppe orders of oxycodone or hydrocodone that were suspicious that it shipped and failed to report to DEA.[432]

237. Cardinal's file for Medicine Shoppe lacks any evidence of adequate due diligence in response to dozens of Medicine Shoppe orders Cardinal reported to DEA as suspicious orders.

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[427] CAH-WV-000770.

[428] P-16643 (2/15/2012 email from Mays to Martin re: Safescript 010052670 A/R Balance 2/13 $48,124.91); 5/18/21 Trial Tr. (Mays) at 138-140, 143-144; 5/19/21 Trial Tr. (Mays) at 145, 189; 5/20/21 Trial Tr. (Moné) at 233.

[429] Howenstein Depo. at 16-17.

[430] Howenstein Depo. at 231-234; P-09882_00028.

[431] P-14294 (2012-2020 Cardinal Health Suspicious Orders Cabell County Pharmacies spreadsheet, Column BG, lines 764, 770, 773, 777, 780, 847, 850, 853, 862, 876, 885, 929, 932, 935, 938, 941, 950, 953, 956, 959, 962, 965, 976, 987, 994, 997, 1000, 1023, 1026, and 1029); P-42071 (Cardinal Health Flagged/Suspicious Orders).

[432] P-42116 (2008-2018 Cardinal Health Due Diligence File on Medicine Shoppe).

In September 2012, Cardinal reported 33 suspicious orders for Medicine Shoppe to the DEA.[433] A review of Medicine Shoppe's due diligence file reflects a dearth of information - just a single email in September 2012 related to a single order from Medicine Shoppe with no indication the email relates to any of the 33 orders reported in September 2012.[434]

238. As it relates to Medicine Shoppe, Cardinal is correct there is a substantial amount of paper in the due diligence file found for this pharmacy.[435] The file consists of 386 pages but lacks any reasonable explanation to dispel this suspicion surrounding the orders in 2012 when Mr. Emma himself labeled Medicine Shoppe as a "black hole," noting the pharmacy had seen significant growth and at least six requests for site visits to validate the growth had been ignored.[436] To the contrary, the due diligence file and on-site investigation conducted in August of 2012 substantiate the presence of additional red flags indicating the likelihood of diversion that Cardinal itself identified.

239. As set out above there is a systemic lack of due diligence around significant events related to Cardinal's customers in Cabell and Huntington, even for the timeframes, June 26, 2010, forward and March 9, 2015, forward, for which Cardinal should have complete due diligence files for its West Virginia and Cabell and Huntington customers.

240. There is no basis in the record for the Court to believe that Cardinal's due diligence files contained additional information at any other point in time, particularly considering

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[433] P-42071 (Cardinal Health Flagged/Suspicious Orders).

[434] P-42116 (2008-2018 Cardinal Health Due Diligence File on Medicine Shoppe).

[435] *Id.*.

[436] P-28038 (6/12/2012 email from Emma to Baber and Quintero re: Follow-up to Training 6-5-2012).

Cardinal's admission in 2012 that its due diligence files were inadequate.[437] This finding is consistent with Mr. Rafalski's testimony that Cardinal's due diligence files were inadequate.[438] It is also significant that Cardinal did not provide any testimony surrounding the adequacy of their due diligence files from any fact or expert witnesses.[439]

241. Mr. Rafalski also offered reliable testimony concerning Cardinal's failure to maintain effective controls against diversion in Cabell County and beyond. Mr. Rafalski testified that Cardinal failed to maintain effective controls to prevent diversion in Huntington-Cabell.[440] Mr. Rafalski further found that Cardinal failed to maintain an effective suspicious order monitoring system in Cabell County and that this deficiency was both systemic and widespread.[441]

3. Cardinal's Suspicious Orders Reported

242. There is no dispute as to whether the Defendants, including Cardinal, had an obligation to report suspicious orders to the DEA. However, there appear to be significant variations in Cardinal's practice of reporting suspicious orders over time that changed as its SOMs changed. Additionally, according to Mr. Moné and the presentation/training he prepared for the system he helped to implement, if there was a suspicious order that could not be cleared by conducting due diligence on the pharmacy customer, then the order remained blocked, the suspicious order was reported to DEA, the sales force for that customer would be notified, and *the*

[437] P-08873_00017 (1/25/2016 email from Giacalone to Callinicos re: DEA related documents and links).

[438] 5/26/21 Trial Tr. (Rafalski) at 102.

[439] Cardinal's expert MacDonald testified that there was some due diligence but admitted that he had not been provided the due diligence files and did not review the same. 7/9/21 Trial Tr. (MacDonald) at 52-53.

[440] 5/26/21 Trial Tr. (Rafalski) at 108:3-14.

[441] 5/26/21 Trial Tr. (Rafalski) at 108:25-109:12.

customer was to be terminated from purchasing controlled substances or in totality.[442] Based on Cardinal's stated policy, the repeated examples below where suspicious orders were reported yet Cardinal continued to service the customer demonstrates blatant violations of their own internal policies and procedures designed to prevent diversion. This especially holds true for Cardinal's largest customer in Cabell and Huntington, Medicine Shoppe, for which Cardinal reported at least 197 suspicious orders of opioids.[443]

243. Cardinal's initial system was based in part on the generation of monthly Ingredient Limit Reports ("ILR"). Each of Cardinal's distribution centers compiled its own ILR each month for the customers that it serviced. This system was in place from the 1990's until 2008, however Cardinal has produced ILRs from the Wheeling, West Virginia distribution center from August 2005 through December 2007 and April 2008.[444] During this timeframe based on the ILRs in the record Cardinal reported to the DEA 259 suspicious orders placed by its customers in Cabell and Huntington.[445] All of these orders were shipped into the community and not reported until after they were already shipped.

244. In 2008 after the DEA first took action against Cardinal, Cardinal revamped its SOMs along with its reporting of suspicious orders. From 2008 until August 2012 Cardinal reported just one suspicious order in Cabell and Huntington, which was an order for an opioid

[442] P-14122_000121-122 (5/6/2008 email from Ramano to Mone re: Anti-Diversion and SOM Training).

[443] P-42071 (Cardinal Health Flagged/Suspicious Orders).

[444] P-14296 (2005-2008 Cardinal Health ILR Limiters (Oxycodone/Hydrocodone) Wheeling, WV Distribution Center).

[445] P-42432 (Aug. 2005-Dec. 2007 and Apr. 2008 Cardinal Suspicious order shipments to Cabell Co.). While Cardinal had a secondary system for reporting suspicious orders as discussed *supra* there does not appear to be any record evidence of suspicious orders being reported out of the Wheeling, West Virginia distribution center based on this secondary system.

placed by Medicine Shoppe in October 2010.[446] The Court is particularly mindful that this time period is when there was significant growth in the volume of opioids coming into Cabell and Huntington and the surrounding areas and Cardinal only report one suspicious order in over four and a half years.[447] Certainly, a four and a half-year period of reporting almost no suspicious orders after reporting 259 in the approximately two-and-a-half years prior would not go unnoticed by any reasonably prudent registrant/distributor. However, there is no indication in the record that anyone at Cardinal recognized or questioned this significant decline in reported suspicious orders.

245. After the DEA began its second enforcement action against Cardinal, the number of suspicious orders reported in Cabell and Huntington significantly increase. From August 2012 through May 2018,[448] Cardinal reported 291 suspicious orders to the DEA from its customers in Cabell and Huntington alone. In 2012, Cardinal reported 115 suspicious orders, in 2013 it reported 86, in 2014 it reported 5, in 2015 it reported 19, in 2016 it reported 34, and in 2017 it reported 32.[449] This supports the conclusion that from 2008 until February 2012, when the DEA initiated its second enforcement action[450] against Cardinal, Cardinal was not complying with its regulatory obligation to report suspicious orders to the DEA in a timely fashion.

[446] P-42071 (row 2) (Cardinal Health Flagged/Suspicious Orders).

[447] P-44711_00009, 00012 (2006-2018 Opioid Shipments to Cabell County).

[448] P-23655 (ABDC's 4th Supp. Objections and Responses to Plaintiffs' 1st Comb. Discovery Requests, Supp. Response to Request No. 3).

[449] P-42071 (Cardinal Health Flagged/Suspicious Orders).

[450] P-08873_00016 (1/25/2016 email from Giacalone to Callinicos re: DEA related documents and links).

4. Cardinal's Volume of Shipments into Cabell County and Huntington

246. Between January 1996 and May 2018, Cardinal distributed over 37 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell and Huntington, a community of 100,000 people.[451]

247. Between 2006 and 2014, Cardinal's monthly average shipments of oxycodone to Cabell and Huntington retail pharmacies was 6,989 dosage units compared to its national average of 4,975 dosage units.[452] In January 2006, Cardinal Health's average shipments of oxycodone to Cabell and Huntington retail pharmacies was 5,120 dosage units compared to its national average of 3,414 – a ratio of approximately 1.5.[453] By April 2010, Cardinal Health's average shipments of oxycodone to Cabell and Huntington had reached 8,559 dosage units compared to its national average of 4,876 dosage units – a ratio of approximately 1.8.[454]

248. During part of this same timeframe, May 2007 to April 2008, Cardinal was using its ILR system described *supra*. The ILRs used thresholds based on the average amount in grams of each drug base code purchased by each class of customers (retail pharmacies, hospitals/managed care, and other) of each respective distribution center.[455] For retail customers, the averages were then multiplied by four to arrive at the ingredient limit for that month for that distribution center.

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[451] P-44711_00024 (2006-2018 Opioid Shipments to Cabell County).

[452] P-43225_00007 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County); 5/10/21 Trial Tr. (McCann) at 132.

[453] P-43225_00007 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County at #1); 5/10/21 Trial Tr. (McCann) at 132.

[454] P-43225_00007 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County at #52); 5/10/21 Trial Tr. (McCann) at 132-133.

[455] The Chemical Handlers manual is designed to identify extraordinary orders of List I chemicals and is not applicable to controlled substances. 5/20/21 Trial Tr. (Moné) at 94-95.

The Wheeling distribution center for this time period saw its ingredient limits for oxycodone more than double from 105 grams to 211 grams.[456] Most significantly, there is no evidence in the record that Cardinal ever acknowledged this growth or made any determination of the legitimacy of these increases out of the Wheeling, West Virginia distribution center.

249. Another set of alarming numbers related to Cardinal's opioid distributions are found in the significantly disproportionate amounts distributed in West Virginia as compared to other states. When shown the numbers comparing different states Mr. Reardon conceded that the extreme differences would justify further investigation but no one at Cardinal had ever brought this to his attention.[457] Some of the more significant numbers from the Courts perspective are set out here:[458]

Oxycodone (dosage units)	**WV** (Pop. 1.85 million)	**TX** (Pop. 25.15 million)	**IL** (Pop. 12.83 million)	**NE** (Pop. 1.83 million)
2006	10,811,545	6,805,370	5,061,495	1,973,580
2007	11,656,300	8,440,025	5,990,380	2,408,300
2008	12,492,000	8,375,180	6,462,980	2,461,340
2009	14,007,220	9,042,740	7,030,820	2,133,460
2010	16,230,580	9,133,540	7,882,120	2,265,680
2011	16,088,380	9,287,220	9,138,360	2,449,620
2012	17,106,680	8,961,340	10,276,670	2,692,220
2013	16,297,440	9,999,290	14,045,350	3,521,300
2014	16,106,240	9,347,640	11,984,120	2,747,080
Total	130,796,385	79,392,345	77,872,295	22,652,580

[456] P-14296 (2005-2008 Cardinal Health ILR Limiters (Oxycodone/Hydrocodone) Wheeling, WV Distribution Center).

[457] Reardon 11/30/18 Depo, at 489-490.

[458] *Id.; see also* P-44318_00001-00004 (U.S. Census Bureau, Population Distribution and Change: 2000 to 2010, March 2011https://www.census.gov/library/publications/2011/dec/c2010br-01.html).

250. This Court considers this information in the context of the fact that Cardinal knew or should have known as of the early 2000's that the Appalachian area and specifically West Virginia were significant areas for abuse and diversion of opioids.[459] With the public recognition of the abuse and non-medical use of opioids in this region Cardinal (as well as the other distributors) should have a heightened level of awareness of the appropriateness of its distributions of opioids into Cabell and Huntington, the State of West Virginia, and the surrounding Appalachian region.

251. An even more granular look at Cardinal's distributions into Cabell and Huntington reveals that Cardinal's pharmacies here were clearly outside the norm, shipping several times more opioids than Cardinal's national monthly average.[460]

Pharmacy	Total Oxycodone 2006-2014 (d.u.)	Average Monthly Shipped (d.u.; 2006-2014)	Cardinal's National Monthly Average (4,975 d.u.)
Medicine Shoppe BT5541760	2,013,500	18,644	3.7 x
CVS #03391 BR4365486	1,543,500	14,292	2.9 x
CVS #04419 BR4301545	1,036,000	9,593	1.9 x
CVS #04425 BR4321787	970,200	8,983	1.8 x
CVS #0348 AR6055025	780,000	7,290	1.5 x

[459] *See supra*; *see also* 5/20/21 Trial Tr. (Moné) at 39-11, 60. Cardinal testified through its 30(b)(6) deposition designee that it was aware of the rising abuse of prescription drugs as early as 2006 when it received the first Rannazzisi letter. Norris, 10/2/20 Depo at 142-143. Cardinal's former head of QRA, Steve Reardon, also testified that he was aware of the opioid epidemic in 2007. Reardon, 11/30/18 Depo at 413-414.

[460] P-43225_00007-00011(2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) .

Pharmacy	Total Hydrocodone 2010-2014[461] (d.u.)	Average Monthly Shipped 2010-2014 (d.u.)	Cardinal's National Monthly Average 2010-2014 (3,282 d.u.)
Fruth #12 BS1588168	1,749,320	29,155	8.9 x
Fruth #5 AF1585922	1,468,470	24,475	7.5 x
Fruth #2 AS7523118	1,147,630	19,127	5.8 x
Fruth #11 BF1434555	771,970	12,655	3.9 x

252. The following chart describes the highest monthly volume of oxycodone Cardinal shipped to certain pharmacies in Cabell and Huntington from 2006 through 2014 compared to Cardinal's average monthly volume for customers nationwide from 2006 through 2014.

Pharmacy	Highest Month (d.u.)	Cardinal's National Average for Pharmacy's Highest Month (d.u.)
Medicine Shoppe BT5541760	34,600 (November 2010)	5,074 (November 2010)
CVS #03391 BR4365486	24,600 (March 2010)	5,283 (March 2010)
CVS #04419 BR4301545	16,600 (December 2013)	6,925 (December 2013)
CVS #04425 BR4321787	14,500 (November 2010)	5,074 (November 2010)
CVS #0348 AR6055025	16,700 (July 2014)	6,827 (July 2014)

253. Cardinal wasn't completely blind to this volume, as in 2012 there was recognition that Medicine Shoppe was a "black hole" related to the distribution of opioids.[462] However, even

[461] Cardinal Health began servicing Fruth Pharmacies in January 2010.

[462] P-28038 (6/12/2012 email from Emma to Baber and Quintero re: Follow-up to Training 6-5-2012).

after discovery of significant red flags Cardinal continued to service Medicine Shoppe with large volumes of opioids.[463]

254. Based on the forgoing, the Court finds that Cardinal Health failed to maintain adequate or effective controls to prevent diversion of prescription opioids into the illicit market in Cabell and Huntington. Cardinal Health failed to design and operate an effective system to identify, block, and report suspicious orders of opioids from pharmacies in Cabell and Huntington. Cardinal Health did not conduct sufficient due diligence in general and specifically as it relates to investigations of the orders Cardinal itself flagged as suspicious. Cardinal Health's failures were systemic and were a substantial factor in the diversion of prescription opioids into the illicit market in Cabell and Huntington.

D. McKesson

255. McKesson has a nationwide distribution model and nationwide policies governing compliance with the CSA, and those policies were to be implemented uniformly across the country.[464]

256. McKesson currently has approximately twenty-eight active distribution centers.[465] Three McKesson distribution centers – McKesson's Landover, MD, Washington Court House, OH, and New Castle, PA facilities – include or have included West Virginia customers among

[463] P-43225_00007-00009 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) .

[464] 5/24/21 Trial Tr. (Oriente) at 40:24-41:7; Walker, 1/10/19 Dep. at 130:24-131:4, 131:23-132:2, 133:9-13, 133:16-20.

[465] *See* 5/25/21 Trial Tr. (Oriente) at 13:1-3.

those they primarily service or have serviced.[466] McKesson's Washington Court House Distribution Center has historically serviced customers from Cabell County.[467]

257. David Gustin had responsibility for CSA compliance for customers serviced by the Washington Courthouse Distribution Center from 2007 to 2014.[468] Overall, David Gustin had responsibility for ensuring compliance for approximately 13,000 distinct McKesson pharmacy customers across 15 states.[469]

1. DEA Enforcement Actions Against McKesson

258. In 2006 and 2007, DEA issued Orders to Show Cause ("OTSC") seeking emergency relief against McKesson for its failure to maintain effective controls against diversion as evidenced in its distribution of opioids from its Lakeland, Florida and Landover, Maryland Distribution Centers. The DEA pointed to failures in compliance that fed the supply of opioids into Appalachia and the Midwest.[470] The DEA also alleged that McKesson had failed to report suspicious orders of controlled substances as required by 21 C.F.R. 1301.74(b).

259. Shortly after, further DEA investigative findings put McKesson on notice that the DEA found systemic failures in its anti-diversion controls.[471] These investigations resulted in

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[466] *See* P-13736A; 5/25/21 Trial Tr. (Oriente) at 22:18-23:2.

[467] 5/24/21 Trial Tr. (Oriente) at 22:18-20.

[468] Gustin, 8/17/18 Depo at 154:18-24.

[469] Gustin, 8/17/18 Depo at 29:2-7.

[470] P-23733 (2008 DEA-McKesson Settlement and Release Agreement and Administrative Memo of Agreement).

[471] Including, *inter alia*, McKesson's distribution centers in Landover, MD (which supplied WV customers) for its distribution of hydrocodone and failure to report suspicious orders, Conroe, TX for selling 2.6 million dosage units of hydrocodone to two pharmacies in seven months and failure to report as suspicious orders, Denver, CO for its sale of large quantities of hydrocodone to three pharmacies and failure to report as suspicious orders, Salt Lake City, UT for sale of large quantities of hydrocodone, oxycodone, fentanyl and methadone and failure to report as suspicious orders,

settlement agreements (MOAs) with McKesson in which McKesson agreed "to maintain a compliance program designed to detect and prevent diversion of controlled substances" as required under the CSA and applicable DEA regulations.[472]

260. In November, 2014, DEA wrote to McKesson concerning its continued nationwide failure to report suspicious orders and to maintain effective controls against diversion following its 2008 settlement with DEA, and provided a detailed list of deficiencies it found were national in scope, including McKesson's failure to "maintain[] ... effective controls against diversion of particular controlled substances," and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[473]

261. In January 2017, McKesson entered into a $150 million settlement agreement with DEA for violations of the CSA associated with virtually all of its distribution centers, including the Washington Courthouse, OH distribution center that shipped opioids to Cabell County. McKesson agreed to a suspension of its license to distribute controlled substances from that distribution center (and others) for two years.[474]

262. Specifically, the settlement agreement noted that the following McKesson distribution centers, including two that serviced customers in West Virginia, failed to maintain

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West Sacramento, CA for failure to report twenty-eight separate thefts or losses of controlled substances.

[472] *See* P-23733 (2008 DEA-McKesson Settlement and Release Agreement and Administrative Memo of Agreement).

[473] P-00122 (Nov. 4, 2014 DEA Letter to McKesson re: Registration Consequences for McKesson Corporation for Violations of the Controlled Substance Act).

[474] *See* P-42554 (2017 DEA-McKesson Settlement Agreement); *id.* at 3, Section 2, Acceptance of Responsibility, ¶ 2. ("McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.").

effective controls against diversion following the May 2008 settlement agreement: Washington Court House, OH; Landover, MD; Aurora, CO; Aurora, IL; Delran, NJ; Lacrosse, WI; Lakeland, FL; La Vista, NE; Livonia, MI; Metheun, MA; Santa Fe Springs, CA; and West Sacramento, CA.[475]

263. As part of the 2017 settlement agreement, McKesson accepted responsibility for not identifying and reporting suspicious orders as required by the CSA and the 2008 settlement agreement with DEA.[476] McKesson has admitted that the systematic failure to report thousands of suspicious orders was "at the core" of the $150 million fine paid by McKesson in 2017.[477]

264. The 2017 settlement agreement further noted that McKesson failed to conduct adequate due diligence and failed to maintain complete and accurate records as required by the CSA and McKesson's Controlled Substances Monitoring Program.[478]

265. The DEA testified that it was "in fact frustrated that registrants were blatantly violating the MOUs[/MOAs] from prior administrative actions."[479]

2. McKesson's Failure to Maintain Adequate and Effective Controls Against Diversion

a. McKesson's Knowledge of its CSA Duties and the Impact of Compliance with the CSA

266. McKesson understood that diversion can be impacted by compliance with the CSA.[480]

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[475] *Id*.

[476] *Id*.

[477] Hartle, 7/31/18 30(b)(6) Dep. at 307:12-309:7.

[478] P-42554 (2017 DEA-McKesson Settlement Agreement).

[479] Prevoznik, 4/18/19 30(b)(6) Dep. at 621:5 to 621:20.

[480] Hartle, 8/1/18 Dep. at 82:9-82:20.

267. McKesson has admitted that it has a duty to report suspicious controlled substances orders to DEA.[481] Additionally, McKesson has admitted it has a duty once it has reported a suspicious order to either block that order or conduct due diligence on the order and only ship once it has determined the order is not likely to be diverted into illegal channels.[482]

268. McKesson has also admitted it has a duty to maintain effective controls against diversion.[483]

269. McKesson at all times had ability to audit pharmacies to assess the volume of controlled substances pharmacies were receiving from other distributors.[484]

270. Assessing red flags involving pharmacy customers is an important tool to prevent diversion. Percentages of controls to non-control purchases, overall volume of pills given the demographics, percentage of cash sales, conducting business with pain clinics, filling out-of-area scripts, and receiving regular threshold increases are all red flags that should be investigated.[485]

b. Section 55 SOMs Program

271. Between 1997 and present, the policies and procedures governing McKesson's suspicious order monitoring system have gone through several transitions. McKesson's first SOM policy was included within Section 55 of the McKesson Operations Manual, which dates back to at least 1997 and continued until January 2009.[486] McKesson distribution centers were to generate a daily and monthly Controlled Substance Suspicious Order Warning Report (also referred to as a

[481] *See* Hartle, 7/31/18 30(b)(6) Dep. at 36:14-36:18, 36:20-36:22.

[482] *See* Hartle, 7/31/18 30(b)(6) Dep. at 38:5-38:19.

[483] *See* Hartle, 7/31/18 30(b)(6) Dep. at 52:22-53:3.

[484] Hartle 8/1 Dep. at 431:5-14.

[485] 5/24/21 Trial Tr. (Oriente) at 65-68.

[486] *See* Hilliard, 1/10/19 Dep. at 163:20-164:1.

DU-45).[487] To qualify for placement on a DU-45 report, the order had to be three-times the rolling 12-month average for that drug at that distribution center.[488]

272. The DU-45 did not detect orders of unusual frequency or outside of a customer's typical pattern. McKesson has not located any DU-45 reports for the Washington Courthouse distribution center and thus has located no suspicious order reports for any customer in Cabell County.[489] While orders appearing on the DU-45 reports were provided to the DEA, these orders were not investigated or blocked but instead were shipped to the pharmacy customers.[490]

273. Under Section 55, McKesson has acknowledged that the DU-45 reports provided to the DEA were excessive orders, rather than true suspicious orders.[491]

274. DEA has confirmed that these reports were not suspicious order reports that complied with the CSA and the reports themselves were not useful to DEA.[492]

275. On September 1, 2005, members of the DEA met with employees of McKesson to discuss DEA's concerns surrounding the supply of controlled substances to internet pharmacies.[493]

276. DEA also provided its general expectations as to suspicious order monitoring and due diligence that should be conducted by McKesson as to all of its customers ordering controlled substances.[494]

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[487] P-07649 (McKesson Drug Operations Manual).

[488] Hilliard, 1/10/19 Dep. at 89:2-12.

[489] 5/26/21 Trial. Tr. (Rafalski) at 105:17-105:21.

[490] Hilliard, 1/10/19 Dep. at 97:21-98:10, 173:15-173:21, 178:20-179:11.

[491] Hilliard 1/10/19 Dep. at 176:8-22; P-08314.

[492] 6/7/21 Trial Tr. (Rannazzisi) at 228:1-9; 229:15-230:12; 231:4-232:5; 6/8/21 Trial Tr. (Rannazzisi) at 110:21-111:24; Prevoznik, 4/18/19 30(b)(6) Dep. at 673-74, 679-680.

[493] *See* P-12805 (Oct. 20 2005 Letter from Mapes to Rannazzisi re: Internet Presentation with McKesson Corp. on Sept. 1, 2005).

[494] *See Id.*

277. At a follow-up meeting with DEA in January 2006 it was revealed that in October 2005 nearly 2 million doses of hydrocodone were distributed by McKesson to six internet pharmacies in an 11 day period.[495] McKesson acknowledged in a meeting with DEA about these purchases that they were not prevented, in part, because McKesson's SOMs program failed to track generic controlled substances.[496] Mr. Rannazzisi testified that McKesson's failure to track generic products as part of its SOMs program demonstrates a "systemic failure" by McKesson.[497] The DEA further described this as an epic failure by McKesson.[498]

C. Lifestyle Drug Monitoring Program

278. In May 2007, as a result of an ongoing DEA investigation, McKesson launched the Lifestyle Drug Monitoring Program (hereinafter "LDMP").[499] The LDMP was limited to four drugs: oxycodone, hydrocodone, alprazolam and phentermine.[500] For each of these four drugs, an 8,000 monthly dosage unit threshold was set for every McKesson customer nationwide. McKesson set this universal threshold, even though, during that same time period, DEA indicated to McKesson that 5,000 doses per month for these four drugs was average.[501]

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[495] *See* P-00051 (Jan 23, 2006 Letter from Mapes to Rannazzisi re: Meeting Between Officer of Diversion Control and McKesson Corp. Jan. 6, 2006).

[496] P-00051 (Jan 23, 2006 Letter from Mapes to Rannazzisi re: Meeting Between Officer of Diversion Control and McKesson Corp. Jan. 6, 2006); Hilliard, 1/10/19 Dep. at 116:8-117:9, 122:20-123:7**;** 6/8/21 Trial Tr. (Rannazzisi) at 18:6-18:18; Walker, 10/10/19 Dep. at 88:20-89:8.

[497] 6/8/21 Trial Tr. (Rannazzisi) at 20:7-12.

[498] Prevoznik, 5/17/19 30(b)(6) Dep. at 848-50.

[499] *See* P-12708 (Lifestyle Drugs & Internet Pharmacies – McKesson Powerpoint Presentation).

[500] *Id*.

[501] *Id*.

279. Once the 8,000 dosage unit threshold was reached in a given month, a three level review process was supposed to be triggered.[502] Counsel for McKesson represented to DEA that once the 8,000 monthly dosage limit was met, due diligence would be conducted before the customer could order further quantities of the drug in question.[503]

280. McKesson admits that if it shipped more than 8,000 pills without conducting due diligence or documentation it would be unlawful conduct.[504] In fact, the LDMP had no mechanism to block orders once the 8,000 unit threshold was met and while an investigation was ongoing.[505]

281. McKesson's internal audits revealed multiple glaring deficiencies with the LDMP. In a July 2007 audit, a McKesson auditor noted that the LDMP may not track all generic controlled substances. The auditor also noted that a customer can use more than one distribution center or more than one account number in order to exceed the 8,000 dosage unit monthly threshold without detection.[506]

282. McKesson even went so far as to set up a call center in Texas called "ServiceFirst," where between 80 and 100 customer service employees made "proactive" calls to McKesson's customers to "ask if they wanted an increase."[507]

283. In an August 2007 audit of the Washington Courthouse Distribution Center, a McKesson auditor found that McKesson employees were unaware that the LDMP applied to retail national accounts or hospital accounts. The auditor further noted a lack of training provided to

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[502] *Id*.

[503] *See* P-23845 (MCKMDL00330924).

[504] *See* Hartle, 7/31/18 30(b)(6) Dep. at 211:11-212:5.

[505] *See* Hilliard, 1/10/19 Dep. at 63:11-13.

[506] *See* P-00098 (MCKMDL00591949).

[507] Gustin Depo 8/17/2008 at 330:6-339:22.

employees regarding the LDMP.[508]

284. Like Section 55 before it, the LDMP failed to satisfy the security, shipping, or reporting requirements in the CSA. McKesson has failed to produce any true suspicious orders that were detected or reported under the LDMP. Moreover, as noted above, the LDMP had no mechanism to block suspicious orders either.

d. Controlled Substances Monitoring Program

285. In the wake of its settlement with the DEA, in April 2008, McKesson implemented its Controlled Substances Monitoring Program ("CSMP"). The CSMP has remained in effect in some form since 2008.

286. With the launch of the CSMP in 2008, McKesson for the first time began systematically blocking controlled substance orders despite being informed by the DEA that this should be done as early as 2005.[509]

287. McKesson did not comply with the CSA following its launch of the CSMP and settlement with DEA in 2008. In fact, this settlement did not deter the company's behavior at all. At the time of CSMP launch, McKesson notified its pharmacy customers that the CSMP would be implemented, but that it would be "business as usual" from the customer's perspective.[510]

288. Thresholds have always been at the core of the CSMP at McKesson.[511]

289. Under the CSMP, thresholds were customer-specific, using the highest of the customer's orders for the preceding 12 months for a given product and adding a 10% buffer beyond

[508] *See* P-42672 (MCKMDL00591251).

[509] Hilliard, 1/10/19 Dep. at 296:19-298:14.

[510] *See* P-08363 (MCKMDL00543610).

[511] Hartle, 8/1/18 Dep. at 122:15-123:1.

that.[512] However, the 10% buffer was the lowest buffer applied to McKesson customers. Some customers received a 25% buffer and other customers received a buffer as high as 30%.[513]

290. Thresholds could then be adjusted thereafter through a process referred to as a threshold change request.[514]

291. Threshold increases were required to be well documented, customer generated, come with an appropriate level of due diligence, and come with a legitimate business justification.[515]

292. However, threshold increases were routinely granted at McKesson with either no due diligence or without the proper due diligence accompanying those increases.

293. In April 2011, David Gustin noted that threshold increases at McKesson had become "almost automatic".[516]

294. In July 2012, Regulatory Affairs Director, Tom McDonald, stated that the company was too liberally granting threshold increases without proper documentation and often based only on a stated claim of business growth by the customer.[517]

295. In April 2013, a McKesson employee noted that "TCRs [threshold change requests] are done same day" and that "TCRs are commonplace."[518]

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[512] 5/24/21 Trial Tr. (Oriente) at 129:1-11.

[513] Hartle, 8/1/18 Dep. at 197:6-198:18; 5/24/21 Trial Tr, (Oriente) at 129:12-129:20.

[514] *See* P-42638 (MCKMDL00518107).

[515] *See* P-07648 (MDKMDL00336532).

[516] *See e.g.,* P-12821; P-22937.

[517] *See* P-08761 (MCKMDL00633455).

[518] *See* P-00054 (MCKMDL00476776).

296. David Gustin, the Director of Regulatory Affairs overseeing Cabell County, even undertook to increase thresholds of pharmacy customers on numerous occasions without those customers even requesting the increases.[519]

297. In fact, thresholds were so easily and routinely increased at McKesson that by 2013 McKesson had to modify the CSMP to make threshold increases the exception, rather than the rule, which had been the case up to that point in time.[520]

298. McKesson has also traditionally set its thresholds so high that they were not an effective tool to detect potential diversion.

299. In August 2011, David Gustin internally stated "I have thought of an area that needs to be tightened up in CSMP and it is the number of accounts we have that have large gaps between the amount of Oxy and Hydro they are allowed to buy (their threshold) and the amount they really need. (Their current purchases) This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be being used for legitimate purchases."'[521]

300. However, it was not until 2015 that McKesson first began systematically reducing opioid thresholds for its customers. For example, in February 2015, oxycodone thresholds were reduced for 2,624 Retail National Account ("RNA") customers with the total reduction equaling 17.1 million doses per month. Oxycodone thresholds were reduced for independent small medium chain pharmacies in May 2015 equaling more than 22 million doses per month.[522]

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[519] P-42626.

[520] P-13737.

[521] *See* P-08309 (MCKMDL00507799).

[522] *See* P-08247 (MCKMDL00402184).

301. In May 2016, McKesson reduced the hydrocodone thresholds for its Rite Aid customers by 24,615,775 doses per month.[523] In July 2017, McKesson reduced the Rite Aid thresholds for hydrocodone, oxycodone, other opioids, and other controlled substances. The reductions for all controlled substances totaled 111,938,870 doses per month.[524]

302. McKesson also systematically worked to reduce the number of orders that were blocked and not shipped to customers. Specifically, in October 2006 McKesson employees discussed creating a threshold warning program to ensure "work could begin on justifying an increase in threshold prior to any lost sales."[525]

303. Beginning with the launch of the CSMP in 2008 this threshold warning program was implemented. Specifically, in April 2008, McKesson notified its pharmacy customers that the CSMP would be implemented as a result of McKesson's settlement agreement with DEA, but that the CSMP would include a notification system that would "deliver communications in plenty of time for your pharmacy to take corrective action, helping head off any potential disruptions in supply."[526]

304. Threshold warning systems were designed solely to ensure that thresholds could be increased before any sales were lost.[527] This strongly suggests that McKesson intended for these

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[523] *See* P-13211 (MCKMDL00340143).

[524] *See* P-13212 (MCKMDL00340151).

[525] *See* P-00097 (MCKMDL00543971).

[526] *See* P-08363 (MCKMDL00543610).

[527] 5/25 Trial Tr. (Ashworth) at 219: (Q: Trial Tr. May 25, 2021 (Ashworth) at 219 (Q: Sir…you as a sales rep would not only call and warn the customer they were getting close to the threshold, but you would actually ask the customer if they wanted to increase their threshold. True? You would ask them if they wanted to increase their threshold after your warning. Is that accurate? A: I would, I would ask if they, they needed a threshold change. And if they did, that would start the whole threshold request procedure.).

thresholds to create the appearance that it had a meaningful Suspicious Order Monitoring System, while the system in practice did very little to detect or prevent shipment of orders of unusual size, pattern, or frequency.

305. It was not until late 2013 that McKesson ceased its threshold warning program. It finally acknowledged internally at that point that providing such warnings was not the best practice for it to be engaged in because doing so allowed customers to manage against a number to avoid detection by McKesson.[528]

306. Once orders were blocked under the CSMP, McKesson was to conduct a three-level review to assess whether the order was suspicious and whether further orders from the customer should be blocked.[529] Level 1 review required contacting a customer when it exceeded its threshold to assess the reason. If any concerns remained about the order, the inquiry was to be escalated to level 2 review, which was conducted by the Director of Regulatory Affairs responsible for oversight. If concerns remained regarding the order, then the review was escalated to level 3, which was to be conducted by the Senior Vice President of Distribution Operations and Regional Senior Vice President.[530] Orders were only reported as suspicious if the customer reached a level 3 review.[531] The overarching purpose of the three-level review was to assess whether an order was suspicious and whether further orders from the customer should be blocked. McKesson's CSMP required that these reviews be documented.

[528] P-13737.

[529] 5/24/21 Trial Tr. (Oriente) at 39:11-40:11; P-42657.

[530] P-42657.

[531] P-42657.

307. Level 1 forms completed for Cabell pharmacies were not completed properly and didn't contain necessary information for McKesson to properly conduct due diligence.[532] There is also no evidence that McKesson conducted any level 2 or level 3 reviews for Cabell County pharmacy customers. This is further supported by the fact that zero suspicious orders were reported to the DEA related to Cabell County customers from the launch of the CSMP in 2008 until mid-2013 when the level 1-3 process was abandoned.[533]

308. Internal McKesson audits revealed further violations of the CSA and CSMP by McKesson specifically as to the Distribution Center that serviced Cabell County customers. For example, a March 2011 internal McKesson audit of the Washington Courthouse Distribution Center demonstrated that Level 1 forms and threshold change request forms were not being consistently completed.[534]

309. McKesson has produced transactional data for all prescription medicines, including opioids, for Cabell County that spans October 1, 2004 to December 31, 2018. From May 23, 2008 to July 31, 2013 McKesson only blocked 143 opioid orders placed by pharmacies in Cabell County.[535]

310. McKesson reported no suspicious orders for any pharmacies in the entire state of West Virginia from May 2008 to July 31, 2013.[536] This is consistent with McKesson's nationwide

[532] 5/25/21 Trial Tr. (Ashworth) at 224:24-226:21; P-28152.

[533] P-42089.

[534] P-00115.

[535] *See* P-42089 (MCKMDL01391127).

[536] *See* P-42089 (MCKMDL01391127).

policy not to report suspicious orders to the DEA from the launch of the CSMP in 2008 until August 2013.[537]

311. Plaintiff's DEA expert testified that McKesson's suspicious order reporting failures extended well before and after the 2008-2013 time frame. Mr. Rafalski testified that McKesson reported 0 suspicious orders to the DEA for Cabell County customers from 1996-2012 and only a total of 74 suspicious orders for Cabell County customers from 2013 through 2018.[538]

312. DEA specifically warned McKesson that its Distribution Center servicing Cabell County was not properly reporting suspicious orders. Specifically, an October 2011 DEA audit of the Washington Courthouse Distribution Center found that McKesson was failing to report suspicious orders from that distribution center in violation of the CSA.[539]

313. McKesson's suspicious order reporting failures did not cease in 2013. Even as late as 2015, McKesson admitted internally that the company was continuing to underreport 1,500 suspicious controlled substance orders per month.[540]

314. The word "suspicious" was taboo at McKesson for years after the CSMP was launched. The CSMP manual beginning in 2008 instructed employees to "refrain from using the word 'suspicious' in communications.'"[541] The manual further noted that "[o]nce McKesson deems an order and/or customer suspicious, McKesson is required to act. This means all controlled

[537] P-00122 ((Nov. 4, 2014 DEA Letter to McKesson re: Registration Consequences for McKesson Corporation for Violations of the Controlled Substance Act).

[538] 5/26 Trial Tr. (Rafalski) at 105:17-106:1.

[539] P-42814.

[540] *See* P-13296 (MCKMDL02104903).

[541] *See* P-00121 (MCKMDL00409224); P-42638.

substances sales to that customer must cease and the DEA must be notified."[542] This passage remained formally part of the CSMP until 2013.[543]

315. As DOJ noted in its August 13, 2014 letter to McKesson, "[l]language such as this confirms that McKesson understood that it has an obligation to report suspicious orders, but that it consciously took steps to avoid having to report."[544]

316. McKesson has agreed with the importance of suspicious order reporting as a means to prevent diversion.[545]

317. The Court finds that the duty to report suspicious orders is an important part of the Defendants' duty to prevent diversion. McKesson's systematic failure to report suspicious orders deprived DEA of the ability to investigate suspicious orders from McKesson in order to attempt to minimize diversion itself.[546] As DEA's former Deputy Assistant Administrator for the Office of Diversion Control, Mr. Rannazzisi explained, "they report the suspicious orders, and then we take the suspicious orders and, and do a follow-up, look at the order, look at the customer."[547]

318. The retail national accounts ("RNAs") are a much larger part of McKesson's business than the independent small medium customers ("ISMC").[548]

319. McKesson's compliance systems were not applied to its RNA customers.

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[542] *See* P-12627 (MCKMDL00002509).

[543] *Id*.

[544] *See* P-00121 (MCKMDL00409224).

[545] Hartle, 8/1/18 Dep. at 54:18-24, 76:22-77:4.

[546] 6/7/21 Trial Tr. (Rannazzisi) at 215:22-216:6; 219:14-220:5; 227:8-12.

[547] 6/7/21 Trial Tr. (Rannazzisi) at 215:24-216:2.

[548] Hartle, 8/1/18 Dep. at 26:15-27:2.

320. McKesson's duties under the CSA are the same to RNA customers as they are with ISMC customers and those duties cannot properly be delegated to McKesson's pharmacy customers.[549]

321. Despite possessing that knowledge, McKesson has not historically requested or obtained dispensing data from its RNA customers.[550]

322. This failure to request dispending data prevented McKesson from being able to monitor for certain red flags by depriving itself the ability to see the doctors writing the prescriptions being filled by the customers as well as not collecting the dispensing data to run controls/non-controls and other relevant percentages of prescriptions being dispensed to detect red flags.[551]

323. McKesson has also deferred to headquarters for each RNA customer to determine if threshold increases were appropriate for their specific store locations.[552]

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[549] Walker, 1/10/19 Dep. at 183:11-23; Boggs, 1/17/19 Dep. at 87:13-88:18.

[550] Walker, 1/10/19 Dep. at 189:25-190:8; see P-12743 (MCKMDL00445881); see P-12836 (MCKMDL00521372). The Court rejects Defendants' suggestion that Distributors were not able to obtain dispensing information. As the head of Defendants' trade association noted discussing an amicus brief field by the association: "The brief details wholesalers' inability to gain insight into the practitioner prescribing and pharmacy dispensing practices du to HIPAA issues. This is not altogether true. We have been using dispensing information to assist us in making informed decisions regarding our customers. We have been able to obtain this information without patient identifiable information. When we have been unable to, we do not access the information. We have also been using a third party that signs a HIPAAA business Agreement with the pharmacy, extracts the information we need and then gives it to us without the patient information." *See* P-09099_00001 (John Grey 5/52012 email to Dale Smith re: HDMA Amicus Brief Cardinal vs. Holder).

[551] Walker, 1/10/19 Dep. at 192:23-195:6.

[552] *See* P-12836 (MCKMDL00521372); P-12743 (MCKMDL00445881).

324. In fact, if a RNA customer requested a threshold increase there was a presumption within McKesson that the RNA customer had conducted the required due diligence surrounding the requested increase.[553]

325. McKesson also increased thresholds for illegitimate reasons for RNA customers. For example, McKesson relied on "Thanksgiving Holiday" as the sole reason to increase 200 RNA customers' thresholds 30% across the board on a permanent basis.[554]

326. McKesson admitted that it had the duty to know its customers as well as the duty to know its customers' customers.[555] Yet, given the lack of information requested and the lack of diligence conducted McKesson has also admitted it was not able to know the customers of its RNA customers.[556]

327. McKesson generally did not conduct site visits for RNA customers.[557] For Cabell County specifically no site for visits for any customer occurred before 2013 whether RNA or ISMC.[558]

328. When an RNA pharmacy customer exceeded its threshold, the communication was strictly with the RNA's national headquarters.[559] In fact, there was no store level communications or observations.[560]

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[553] P-12743.

[554] *See* P-42516.

[555] Walker, 1/10/19 Dep. at 199:2-199:11.

[556] Walker, 1/10/19 Dep. at 200:11-19.

[557] Walker, 1/10/19 Dep. at 201:7-14.

[558] 5/25/21 Trial Tr. (Ashworth) at 215:2-215:18.

[559] Walker, 1/10/19 Dep. at 212:17-213:14.

[560] Walker, 1/10/19 Dep. at 190:20-24.

329. McKesson relied on the headquarters of the RNA customers to perform due diligence when a pharmacy exceeded its threshold.[561] McKesson would further assume the RNA customers had conducted their own due diligence when granting them threshold increases.[562]

330. McKesson also never conducted level 1 reviews for RNA customers as required by its own CSMP.[563] Nor did McKesson complete client questionnaires when onboarding new RNA pharmacy customers.[564]

331. Despite its reliance on and deference to its RNA customers McKesson was never made privy to the specifics of any RNA customer's SOMs program.[565]

332. The DEA was not told by McKesson that it allowed RNA customers to monitor themselves under its CSMP.[566]

333. The most prominent example of deference and delegation to RNA customers in Cabell County involves Rite Aid. First, McKesson applied a 30% buffer to Rite Aid's threshold numbers rather than the usual 10% buffer provided to other customers.[567]

334. Without any due diligence or investigation, McKesson also allowed Rite Aid automatic threshold increases for schedule II controlled substances, including oxycodone products. These increases were specifically provided to three Rite Aid stores in Cabell County.[568]

335. McKesson was aware that Rite Aid self-distributed hydrocodone to its stores

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[561] Walker, 1/10/19 Dep. at 203:21-204:1.

[562] Walker, 1/10/19 Dep. at 191:22-192:15.

[563] *See* P-00116.

[564] *Id.*

[565] Walker, 1/10/19 Dep. at 225:17-226:12.

[566] Walker, 1/10/19 Dep. at 214:6-12.

[567] *See* P-12967 (MCKMDL00627168).

[568] *See* P-42728a; 5/24/21 Trial Tr. (Oriente) at 169:10-17, 170:1-3.

including those in Cabell County. However, McKesson never requested this self-distribution data from Rite Aid.[569] Therefore, all of the hydrocodone supplied to Rite Aid stores nationally and in Cabell County was done without the knowledge of whether the total of amount of hydrocodone being received by these Rite Aid stores was appropriate and not indicative of diversionary activity.

336. Rite Aid was provided threshold warning reports that assisted Rite Aid in ensuring its orders would not end up being blocked for exceeding thresholds.[570]

337. McKesson has produced no due diligence files for any Rite Aid customers in Cabell County despite Rite Aid being by far its largest non-hospital account in the County.

338. Plaintiffs' diversion investigation expert, Mr. Rafalski, found that there was no evidence of sufficient due diligence as to Rite Aid stores in Cabell County generally or specifically as to McKesson's decisions to increase opioid thresholds for those customers.[571]

339. From 2006-2014, Rite Aid stores in Cabell County obtained 2,396,440 dosage units of oxycodone from McKesson and obtained 843,040 dosage units of hydrocodone from McKesson.[572] Those totals were in addition to the 5,545,020 dosage units of hydrocodone Rite Aid distributed to itself for those pharmacies, resulting in 8,784,500 dosage units of hydrocodone and oxycodone to these four stores.[573]

340. McKesson made per-pharmacy monthly oxycodone shipments averaging 4,294 dosage units nationally, 4,559 dosage units in West Virginia, and 4,467 dosage units in Cabell and

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[569] 5/24/21 Trial Tr. (Oriente) at 225:24-226:15.

[570] 5/24/21 Trial Tr. (Oriente) at 123:12-125:11.

[571] 5/26/21 Trial Tr. (Rafalski) at 106:2-11.

[572] P-43225 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County).

[573] *Id.*

Huntington.[574] Yet its shipments to the Rite Aid #968 pharmacy store in Huntington averaged 7,552 dosage units per month.[575] This is over 1.5 times McKesson's national, West Virginia, and Cabell and Huntington averages. This difference between McKesson's national shipping average and its Rite Aid #968 average also represents an excess of almost 40,000 dosage units of oxycodone per year that McKesson shipped into Cabell and Huntington.

341. Plaintiffs' diversion control expert, Mr. Rafalski, testified that there was no evidence in the record that McKesson conducted sufficient due diligence of the Rite Aid stores in Cabell and Huntington and of other Cabell customers when increasing thresholds of hydrocodone for those stores.[576] He also found no evidence that McKesson was sufficiently monitoring Rite Aid's self-distribution of hydrocodone to its stores in Cabell and Huntington.[577] He further found no evidence that McKesson had conducted an appropriate Level I or Level II review for its retail national account customers in Cabell and Huntington.[578]

342. McKesson also failed to meet its CSA obligations as it related to its ISMC customers. The best example of this failure comes from its pharmacy customer Custom Script, located in Barboursville in Cabell County, which had a 2010 population of 3,964.[579]

343. McKesson increased the oxycodone thresholds for Custom Script three times in four months in 2010 ultimately increasing the oxycodone thresholds for that customer from 8,000

[574] *See* 43225_0013.

[575] *Id.*

[576] 5/26/21 Trial Tr. (Rafalski) at 106:7-11.

[577] 5/26/21 Trial Tr. (Rafalski) at 106:12-107:2.

[578] *Id.* at 106:23-107:2.

[579] ECF No. 1433-7.

dosage units per month to 30,500 dosage units per month.[580] McKesson offered no due diligence documentation related to any of these threshold increases outside of a single threshold change request form, which is discussed in detail below. In fact, the only documented diligence done on Custom Script didn't even occur until 2013, which was well after the opioid ordering by Custom Script had significantly decreased.[581]

344. The final increase in 2010 took Custom Script's oxycodone threshold from 23,500 to 30,500 dosage units per month. The only reason provided for this increase by Custom Script was that it expected increased oxycodone sales due to marketing it was conducting targeting local physicians, including pain management physicians.[582]

345. Two of the pain clinic physicians Custom Script was working with (Dr. Fisher and Dr. Webb) had faced prior license suspensions, but there is no evidence that McKesson ever investigated this information.[583] In fact, one of the pain management doctors faced medical practice restrictions for improper opioid prescribing years before Custom Script began filling his opioid prescriptions.[584] The other engaged in excessive opioid prescribing, for which he was disciplined, which again was not investigated by McKesson.[585]

[580] *See* P-13712 (MCKMDL00328705).

[581] P-13284.

[582] *See* P-13714 (MCKSTCT00137351).

[583] 5/25/21 Trial Tr. (Ashworth) at 250:14-251:6; P-13284.

[584] 6/15/21 Trial Tr. (Keller) at 122:24-123:13.

[585] 6/15/21 Trial Tr. (Keller) at 117:17-118:4, 135:23-137:6.

346. Data available to McKesson further demonstrated that Dr. Webb and Dr. Fisher were outlier opioid prescribers who were prescribing opioids at exceedingly high levels yet there is no evidence that McKesson sought out this data.[586]

347. In 2011 alone, Custom Script purchased 159,720 dosage units of oxycodone from McKesson. Testimony offered at trial confirmed this number was above average for a McKesson customer.[587]

348. Transactional data also indicates that Custom Script predominantly purchased oxycodone at the 30mg dose, which is another red flag for potential diversion.[588] There is no evidence that McKesson investigated this red flag.[589]

349. Further, from May 2011 to March 2012 Custom Script's controlled substance to prescription ratios consistently remained at or above 90%. There is no evidence that this red flag was investigated by McKesson.[590] This is all the more concerning given the testimony from Mr. Oriente that any customer with a 90% controls to purchases ratio should automatically be let go as a customer by McKesson.[591] Mr. Ashworth further testified that any controls to overall purchase ratio over 50% is high and that he found out in trial preparation for the first time that Custom Script's ratio was over 90% for a period of time.[592]

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[586] 6/15/21 Trial Tr. (Keller) at 116:16-118:4, 129-133, 137:1-6.

[587] 5/25/21 Trial Tr. (Ashworth) at 251:9-252:3.

[588] P-12643.

[589] P-13284; 5/25/21 (Ashworth) Trial Tr. at 215:2-18.

[590] *See* P-13710 (MCKMDL00326665); 5/24/21 (Oriente) Trial Tr. at 217:13-24.

[591] 5/24/21 (Oriente) Trial Tr. at 217:13-24.

[592] 5/25/21 Trial Tr. (Ashworth) at 249:11-250:13.

350. McKesson also improperly interjected its sales force into the CSMP program. McKesson expected its sales representatives to be the eyes and ears of the company as it pertained to potential diversionary conduct by its customers.[593]

351. DOJ specifically found in 2014 that McKesson's desire for increased sales and retaining its customers overrode its obligations to report suspicious orders.[594]

352. DOJ also found that "[w]hile a great deal of effort went into getting sales reps to increase sales, little or no effort was spent on training these sales reps to ensure compliance with the CSA."[595]

353. The improper interjection of the sales force into the CSMP program in Cabell County was illustrated through the testimony of McKesson's sales representative with responsibility for Cabell County customers – Tim Ashworth.

354. Mr. Ashworth testified that he would proactively call on his pharmacy customers to advise them that they were approaching their threshold and inquired whether they wanted to receive a threshold increase in order to continue receiving controlled substances in an uninterrupted fashion.[596]

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[593] *See* P-13385 (MCKSTCT00038337).

[594] *See* P-00121 (MCKMDL00409224).

[595] *Id*.

[596] 5/25/21 Trial Tr. (Ashworth) at 219:9-23. Regulatory Affairs Director Michael Oriente described in an email dated June 30, 2009, that he was "in the eye of the storm" reviewing threshold change requests from customers at the end of the month which was a busy time for threshold change reviews and determining whether or not they should be granted.[596] Mr. Oriente further expressed concern that "sooner or later, hopefully later we will be burned by a customer who did not get enough due diligence. I feel it is more of when than if we have a problem rise up." P-08763 at 2. Trial Tr. May 24, 2021 (Oriente) at 145-146.

355. Evidence offered at trial demonstrated that Mr. Ashworth failed to properly conduct level 1 investigations.[597] This is a key failure because if concerns were not escalated through the level 1 review process, then no further investigation would be conducted by McKesson, that customer's orders would not be reported to DEA as suspicious, and McKesson would continue to provide opioid products to that customer.

356. McKesson's excessive shipments of opioids to customers in counties surrounding Cabell County further contributed to the opioid epidemic in Cabell County and provide further evidence of widespread non-compliance with the CSA by McKesson.

357. For example, McKesson shipped millions of oxycodone and hydrocodone pills in 2006 and 2007 to Sav-Rite in Kermit, WV, which had a population of 406 people.[598] The DEA has testified that there is no scenario in which the town of Kermit had a medical need that justified the supply of this many opioid pills.[599]

358. McKesson shipped 5.8 million oxycodone and hydrocodone pills from 2006-2014 to Family Discount Pharmacy in Mt. Shamrock, which had a population of 1,700 people.[600]

359. McKesson's sales to pharmacies in nearby counties undoubtedly contributed to diversion in Cabell and Huntington. As further examples, from 2006 to 2014, in nearby Chapmanville, W.Va., a Logan County city 55 miles away with a 2010 population of 1,256, McKesson distributed 823,900 dosage units of OxyContin to Chapmanville Pharmacy, a monthly average of 15,844.[601] The distributions of hydrocodone follow the same pattern. McKesson

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[597] P-28152; 5/2/215 Trial Tr. (Ashworth) at 224:24-226:21.

[598] Hartle, 8/1 Dep. at 450:21-453:8.

[599] Prevoznik, 4/18/19 30(b)(6) Dep. at 606-07.

[600] Hartle, 8/1 Dep. at 471:5-473:1.

[601] 43255_00013

distributed 3,306,110 dosage units of hydrocodone with a monthly average of 63,579 to Chapmanville Pharmacy, and 2,106,860 dosage units of hydrocodone with a monthly average of 40,517 to Man Pharmacy.[602] Logan County's entire population was 32,019 in 2010. McKesson's distributions to those three pharmacies would allow for 329 pills to every Logan County resident.

360. Overall, McKesson shipped 299.87 million dosage units of OC and HC to WV from 2005 to 2016.[603]

361. On November 4, 2014, DEA provided a letter to McKesson concerning its "nationwide" failure to report suspicious orders and to maintain effective controls against diversion following its 2008 settlement with DEA.[604] DEA further noted that it "remained concerned that McKesson fails to appreciate the serious and systemic nature of the CSA-related problems that DEA has observed in its several investigations into your client's operations."[605]

362. DEA further found as to McKesson's Washington Courthouse Distribution Center that "McKesson's inability to instill a culture of compliance – even within its compliance operations – may explain why McKesson WCH [Washington Courthouse] did not report anything suspicious about Community Drug of Manchester, Kentucky – a pharmacy located in a town of less than 1,000 adult residents – ordering 20,000 to almost 50,000 dosage units of oxycodone products on a monthly basis in 2011. Indeed, McKesson WCH only took action to reduce this pharmacy's threshold for oxycodone products after receiving a top from the state pharmacy board that it was under investigation. Even after McKesson WCH was aware that this pharmacy was

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[602] 43255_00013

[603] Prevoznik, 5/17/19 30(b)(6) Dep. at 967-68.

[604] *See* P-00122 (Nov. 4, 2014 DEA Letter to McKesson re: Registration Consequences for McKesson Corporation for Violations of the Controlled Substance Act)..

[605] *Id.*

under investigation, it continued to supply it with controlled substances while apologizing for having to reduce thresholds and promising to 'bump up' those thresholds as soon as they could justify doing so. In September 2012, federal and state law enforcement officers executed a search warrant on Community Drug as part of an investigation that ultimately resulted in the criminal conviction of the lead pharmacist and his wife. Days after that search warrant was executed (and covered by local television news outlets), McKesson WCH contacted Community Drug telling it that it would be seeking a 'pretty sizable increase' in the oxycodone and hydrocodone thresholds for this store."[606]

363. As previously noted, in January 2017, McKesson entered into a $150 million settlement agreement with DEA for Controlled Substance Act violations at various Distribution Centers.[607] In order to placate and satisfy its customers' demands, and even after admitting failures in the 2017 settlement, on January 30, 2017, Senior Director of Regulatory Affairs, Nate Hartle, noted that despite the 2017 settlement agreement it would still be "business as usual from a threshold perspective" at McKesson.[608]

364. As outlined in the 2017 settlement, McKesson's Washington Court House Distribution Center, which serviced customers in Cabell County, failed to maintain effective controls against diversion, and failed to report suspicious orders from 2009-2017.[609] As a result, of the 2017 settlement, the Washington Court House Distribution Center lost its DEA license for two years.[610]

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[606] *Id.*

[607] P-42554 (2017 DEA-McKesson Settlement Agreement).

[608] P-00026 (MCKMDL00418094).

[609] P-42554 (2017 DEA-McKesson Settlement Agreement).

[610] *Id.*

365. Plaintiffs' diversion investigation expert, Mr. Rafalski offered reliable testimony concerning McKesson's failure to maintain effective controls against diversion in Cabell County and beyond. Mr. Rafalski testified that McKesson failed to maintain effective controls to prevent diversion in Huntington-Cabell.[611] Mr. Rafalski further found that McKesson failed to maintain an effective suspicious order monitoring system in Cabell County and that this deficiency was both systemic and widespread.[612]

3. McKesson's Long-Held Knowledge of the Opioid Epidemic

366. McKesson has admitted that:

- The purpose of CSA's closed system is to prevent diversion and, if you do not follow the CSA's requirements, diversion can result;[613]
- The more pills shipped, the more potential for diversion there is;[614]
- Diversion can increase with failure to maintain effective controls;[615]
- That "one of the foreseeable harms of engaging in unlawful conduct in the distribution of prescription opioids is diversion";[616]
- Illegal distribution of controlled substances has a substantial and detrimental effect on health and welfare of public;[617]
- That diversion migrates across state lines;[618]

[611] 5/26/21 Trial Tr. (Rafalski) at 108:15-24.

[612] 5/26/21 Trial Tr. (Rafalski) at 108:25-109:12.

[613] *See* Hartle, 7/31/18 30(b)(6) Dep. at 57-59.

[614] *See* Hartle, 7/31/18 30(b)(6) Dep. at 268 (using common sense and basic logic, can assume that the more pills shipped, the more potential for diversion there is); *see also* Hartle, 8/1/18 Dep. at 84-85 ("pretty common sense" that diversion lessens without sustained sources of CS supply).

[615] *See* Hartle, 8/1/18 Dep. at 85.

[616] *See* Hartle, 7/31/18 30(b)(6) Dep. at 364.

[617] *See* Hartle, 7/31/18 30(b)(6) Dep. at 41-44.

[618] *See* Hartle, 8/1/8 Dep. at 319-23.

- That Oxycontin, Hydrocodone and other lifestyle drugs are highly abused and found in illegal internet pharmacies;[619]
- It understood there was a prescription drug epidemic in 2012 and that today there is an illicit Fentanyl and heroin epidemic;[620]
- The public health dangers with diversion of controlled substances has been well-recognized for years by Congress, DEA, HDMA, public health authorities;[621]
- The rate of opioid deaths has historically corresponded directly with the rate of opioid sales;[622]
- The prescription opiate epidemic is a hazard to the public health and safety;[623]
- The prescription opioid epidemic has dwarfed other historical disasters;[624]
- "[E]very component of the distribution chain has been breached";[625]
- McKesson "played a role" in fueling the epidemic;[626]
- Opioid addiction is a direct gateway to illicit heroin use;[627] and that
- Distributors have power to stop diversion by controlling the supply of pills and complying with the CSA.[628]

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[619] *See* 5/24/21 Trial Tr. (Oriente) at 33-34.

[620] *See* 5/24/21 Trial Tr. (Oriente) at 63-65.

[621] *See* Hartle, 7/31/18 30(b)(6) Dep. at 278.

[622] *See* Hartle, 7/31/18 30(b)(6) Dep. at 293 ("The volume of opioids in the market and diversion is related to opioid deaths, certainly").

[623] *See* Hartle, 7/31/18 30(b)(6) Dep. at 366.

[624] P-16210 (McKesson PowerPoint).

[625] *Id.*

[626] Hartle 7/31/18 30(b)(6) Dep. at 285:6-286:15.

[627] Hartle, 8/1/18 Dep. at 480 (McKesson aware that once people are addicted to prescription opioids, their likelihood of taking heroin dramatically increases); *see also* P-00014 (Sept. 2017 Controlled Substance Monitoring – Discount Drug Mart – McKesson Powerpoint Presentation). In fact, members of McKesson's regulatory department went as far as to make light of this transition as being a good thing because it meant that McKesson no longer had to monitor those people as part of its CSMP. *See also* P-16690 (2/2/2014 email from Gustin to Mahoney, MacDonald, Jonas, Oriente, and Hilliard re: Google alert – hydrocodone, oxycodone).

[628] *See* P-16210 (McKesson PowerPoint).

367. McKesson further understood that the opioid epidemic was having a disproportionate impact in West Virginia and that one of the reasons for the influx of pills and harm to West Virginia was the migration of opioids via the "Oxy Express" or "Blue Highway."[629] McKesson readily, though internally, acknowledged this migration of opioids into places like West Virginia as well.[630]

368. Based on the forgoing, the Court finds that McKesson failed to maintain adequate or effective controls to prevent diversion of prescription opioids into the illicit market in Cabell and Huntington. McKesson failed to design and operate an effective system to identify, block, and report suspicious orders of opioids from pharmacies in Cabell and Huntington. McKesson did not conduct sufficient due diligence in general and specifically as it relates to investigations of the orders McKesson itself flagged as suspicious. McKesson's failures were systemic and were a substantial factor in the diversion of prescription opioids into the illicit market in Cabell and Huntington.

E. Plaintiffs' Expert Opinions on Defendants' SOMs and Shipments

369. Distributors are part of a closed system of registrants authorized to handle controlled substances.[631] Under the closed system, it is the responsibility of the registrants to detect the diversion of controlled substances, including prescription opioids.[632]

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[629] P-00003 (MCKMDL00407451); P-00003 (Prescription Drug Abuse: The National Perspective – McKesson Powerpoint Presentation) (MCKMDL00407451); *see also* Hartle, 8/1/18 Dep. at 318:24-319:10, 319:25-320:16, 320:18-320:20.

[630] P-00003 (Prescription Drug Abuse: The National Perspective – McKesson Powerpoint Presentation); Hartle, 8/1/18 Dep. at 318:24-319:10, 319:25:320:16, 320:18-320:20; 5/20/21 Trial Tr. (Mone) at 113.

[631] 5/26/21 Trial Tr. (Rafalski) at 17:20-18:11.

[632] 5/27/21 Trial Tr. (Rafalski) at 42:23-43:1.

370. Congress enacted the CSA recognizing that the Government lacks the capacity to oversee every narcotic transaction and depends upon the registrants to do so. As Plaintiffs' history of opiate use and abuse and drug policy expert, Dr. David Courtwright, testified: "There were half a million people who were registered under the Controlled Substances Act. Government did not have enough agents to oversee every narcotic transaction. It needed help. And that's why the law is written the way it is."[633]

371. As of 2016, the DEA had only one tactical diversion squad for the entire state of West Virginia, which had 10,000 DEA registrants.[634] It is the responsibility of the manufacturers and distributors to monitor for suspicious orders placed by pharmacies.[635]

372. The "general framework" of the methodology Plaintiffs' diversion investigation expert, Mr. Rafalski, used as a Diversion Investigator at the DEA was to assemble and review the transactional data, obtain policy and procedure documents (including Suspicious Order Monitoring System); conduct interviews to determine if the employees knew and followed the policies and procedures as well as a verbal description of the Suspicious Order Monitoring process; collect customer files; collect internal documents including documents, e-mails and other communications about the handling of controlled substances; and review reported suspicious orders as well as any stopped or held orders. Once he collected this data and information, he determined whether the registrant had effective controls to prevent the diversion of controlled substances, including whether the registrant had designed and operated a suspicious order monitoring system "that was functioning and was able to actually accomplish the mission of

[633] 5/5/21 Trial Tr. (Courtwright) at 43:11-44:1.

[634] 5/27/21 Trial Tr. (Rafalski) at 43:17-44:2.

[635] 5/27/21 Trial Tr. (Rafalski) at 44:3-12.

blocking a suspicious order." Once he made his findings, the findings were memorialized in a report which was processed through the DEA where a decision was made by Chief Counsel about how or if to proceed.[636]

373. In DEA's investigation of Harvard Pharmaceuticals, Rafalski reviewed "a couple dozen customer files," which are also called due diligence files as part of his evaluation of whether Harvard was "maintaining effective controls for the prevention of diversion."[637]

374. Rafalski's role in this case was "to do the same thing I did when I was working at the DEA," including examination of the "same types of records and documents" with respect to the named Defendants and to give his opinion whether the named Defendants "maintained effective controls to prevent the diversion of controlled substances."[638] In this case, depositions of the Defendants' employees were substituted for the interviews he would typically have conducted as part of his investigations while a Diversion Investigator with the DEA.[639]

375. The documents and information Rafalski reviewed and relied upon in forming his opinions in this matter included: Defendants' discovery responses; summaries of transactional data; each Defendant's policies and procedures; each Defendant's Suspicious Order Monitoring Systems; depositions; each customer file produced by each Defendant; Defendants' internal documents; and the Defendants' suspicious orders reported or blocked.[640] He reviewed all due diligence files and all customer files produced by each Defendant in this case as well as the flagged

[636] 5/26/21 Trial Tr. (Rafalski) at 26:6-25 and 27:4-29:16.

[637] 5/26/21 Trial Tr. (Rafalski) at 23:14-21.

[638] 5/26/21 Trial Tr. (Rafalski) at 29:17-30:7.

[639] 5/26/21 Trial Tr. (Rafalski) at 36:8-16.

[640] 5/26/21 Trial Tr. (Rafalski) at 42:7-23.

orders.[641] He also reviewed the actual suspicious orders reported by each Defendant to the DEA that were disclosed in the litigation.[642]

376. Defendants' contentions to the contrary[643] thus are incorrect.

377. Mr. Rafalski utilized and relied upon certain guidance materials in forming his opinions, including: 1) NWDA SOMs (1984)[644]; 2) DEA Investigator's Manual (1996)[645]; 3) 1998 Reno Report[646]; 4) DEA Chemical Handler Manual (2004)[647]; 5) DEA Linden Barber Memorandum (2007)[648]; 6) *Southwood Pharmaceuticals, Inc.* (2007)[649]; 7) HDMA Industry Compliance Guidelines (2008)[650]; 8) Cardinal Health vs. Holder (2012)[651]; 9) *Masters Pharmaceutical vs. DEA* (2017)[652]; 10) DEA Rannazzisi Letters (September 27, 2006 and December 27, 2007)[653]; 11) DEA Administrative actions against each Defendant[654]; and CSA and CFR materials.[655]

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[641] 5/26/21 Trial Tr. (Rafalski) at 102:4-13; 115:8-12).

[642] 5/26/21 Trial Tr. (Rafalski) at 102:18-24.

[643] *See*, *e.g.*, 5/26 Trial Tr. (Rafalski) at 115:8-12; 7/27 (Closings) 131:9-12; 7/28 (Closings) 49:17-22, 51:15-16 and 108:9-11).

[644] P-2094; 5/26/21 Trial Tr. (Rafalski) at 37:14-38:1.

[645] P-8861-00008; 5/26/21 Trial Tr. (Rafalski) at 38:2-5.

[646] P-28295; 5/26/21 Trial Tr. (Rafalski) at 38:6-14.

[647] P-28211; 5/26/21 Trial Tr. (Rafalski) at 38:15-23.

[648] P-8861-00013; 5/26/21 Trial Tr. (Rafalski) at 38:24-39:4.

[649] 72 Fed. Reg. 36487 (2007); 5/26/21 Trial Tr. (Rafalski), 39:5-13.

[650] P-00629; 5/26/21 Trial Tr. (Rafalski) at 41:2-10.

[651] 846 F.Supp.2d 203(D.D.C. 2012); 5/26/21 Trial Tr. (Rafalski) at 39:5-13 and 40:23-41:1.

[652] 861 F.3d 206 (D.D.C. 2017); 5/26/21 Trial Tr. (Rafalski) at 39:5-13 and 40:23-41:1.

[653] 5/26/21 Trial Tr. (Rafalski) at 41:11-13.

[654] 5/26/21 Trial Tr. (Rafalski) at 41:14-15.

[655] 5/26/21 Trial Tr. (Rafalski) at 41:16-20.

378. The transactional data available to Rafalski included: McKesson from 2004 through 2018; AmerisourceBergen from 2002 through 2018; Cardinal from 1996 through 2018 and ARCOS data from 2006 through 2014.[656]

379. Rafalski's findings with respect to the transactional data available for Cabell and Huntington were as follows:

- Cardinal - 92,915 transactions; hydrocodone pills 17,923,260 and oxycodone pills 17,187,905;[657] Sharp increase in 2010 distribution caused by acquiring Fruth business.[658]

- McKesson – 18,862 transactions; hydrocodone pills 3,732,930 and oxycodone pills 3,983,350.[659]

- ABDC – not read into record;[660] trend was steep incline through 2010, with drop-off thereafter caused by Fruth changing distributors – beginning to order from Cardinal.[661]

- No evidence that any Defendant monitored its distribution of hydrocodone or oxycodone into the City of Huntington or Cabell County, West Virginia.[662]

380. Generally, pre-2008, the Defendants each sent excessive purchase reports to the DEA post-shipment.[663] Excessive purchase reports were based on Defendants each setting an average order number nationally based on a 12-month average.[664]

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[656] 5/26/21 Trial Tr. (Rafalski) at 45:3-18.

[657] 5/26/21 Trial Tr. (Rafalski) at 49:4-10.

[658] 5/26/21 Trial Tr. (Rafalski) at 56:16-57:3.

[659] 5/26/21 Trial Tr. (Rafalski) at 49:18-24.

[660] *See* 5/26/21 Trial Tr. (Rafalski) at 47:17-49:3.

[661] 5/26/21 Trial Tr. (Rafalski) at 54:23-55:8.

[662] 5/26/21 Trial Tr. (Rafalski) at 58:25-59:9.

[663] 5/26/21 Trial Tr. (Rafalski) at 61:3-10.

[664] 5/26/21 Trial Tr. (Rafalski) at 62:2-6.

381. Generally, between 2007 and 2008, Defendants' Suspicious Order Monitoring Systems changed to include computerized systems that set a trigger or threshold to flag orders over the threshold and to hold the orders prior to shipment.[665] An order that hits or exceeds the pre-determined threshold raises the suspicion that the order could be diverted.[666] The maintenance of effective controls to prevent diversion requires that once an order is identified by the Defendant's system as suspicious, the order must be held so that a decision can be made about whether the order can be safely shipped.[667]

382. Due diligence is a term for the internal investigation that must take place to review the available information, facts, and circumstances of the order. If the suspicion that the order is likely to be diverted into illicit hands can be dispelled through the investigative process, the suspicion is dispelled, and the order can be shipped.[668] If the suspicion that the order will likely be diverted cannot be dispelled through sufficient due diligence investigation, the order must be blocked, cancelled, and reported to the DEA.[669]

383. According to the Defendants' policies and procedures, if an order is flagged or triggered by the system, not only the triggering order but all subsequent orders within the same drug family must be held or stopped unless or until the suspicion of diversion can be dispelled.[670]

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[665] 5/26 Trial Tr. (Rafalski) at 75:8-23.

[666] 5/26/21 Trial Tr. (Rafalski) at 76:2-20.

[667] 5/26/21 Trial Tr. (Rafalski) at 76:2-20.

[668] 5/26/21 Trial Tr. (Rafalski) at 76:2-20, 103:25-104:13.

[669] 5/26/21 Trial Tr. (Rafalski) at 76:2-20.

[670] 5/26/21 Trial Tr. (Rafalski) at 77:8-14; 78:9-14; 79:10-25 and 80:2-6.

If a suspicious order is not blocked and the suspicion is not dispelled, more likely than not, diversion will occur.[671]

384. According to the applicable suspicious order monitoring regulation, registrants like the Defendants are required to identify orders of unusual size, deviating from a normal pattern or of an unusual frequency. However, Defendants' systems only monitored the volume of controlled substances ordered.[672] The triggering system should be designed to identify an order that is suspicious of being diverted because it is outside of what is usual or normal for each customer.[673]

385. Rafalski identified six flagging methodologies used by Defendants or other DEA registrants and/or accepted by federal courts, and had the methodologies run against the available data.[674] Methodologies A and B are versions of the system used by Masters Pharmaceuticals, as set forth in the U.S. Court of Appeals' ruling.[675] Methodology C is based on a flagging system used by Mallinckrodt, PLC, an opioid and other prescription drug manufacturer.[676] Methodology D was used at various times by all three Defendants.[677] Methodology E is based on a policy that was used by Defendant McKesson.[678] Methodology F is based on a policy that was used by Defendant Cardinal.[679]

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[671] 5/26/21 Trial Tr. (Rafalski) at 104:7-13.

[672] 5/26/21 Trial Tr. (Rafalski) at 82:18-83:5.

[673] 5/26/21 Trial Tr. (Rafalski) at 82:18-83:5 and 84:12-19.

[674] 5/26/21 Trial Tr. (Rafalski) at 84:20-23.

[675] 5/26/21 Trial Tr. (Rafalski) at 85:3-11; *Masters Pharms., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

[676] 5/26/21 Trial Tr. (Rafalski) at 85:12-14.

[677] 5/26/21 Trial Tr. (Rafalski) at 85:15-17.

[678] 5/24/21 Trial Tr. (Oriente) at 31:23-32:3; 34:12-25.

[679] 5/26/21 Trial Tr. (Rafalski) at 57-58; P-09320 (Cardinal's DEA Compliance Manual) at bates page 01383939 (describing policy).

386. Methodology A – "Maximum monthly trailing six-month threshold looks back at six months of data and sets the threshold at the highest order amount in the prior six months.[680] If an order exceeds the highest order amount in the prior six months, the system triggers or flags the order and holds the order pending review or the execution of due diligence sufficient to dispel the suspicion that the order is likely to be diverted.[681] If no due diligence is performed all subsequent orders should be held and not shipped.[682]

- ABDC — Oxycodone dosage units flagged 11,610,920 – 90.6%
  Hydrocodone dosage units flagged 20,621,360 – 91.1%[683]
- Cardinal — Oxycodone dosage units flagged 15,997,400 – 93.1%
  Hydrocodone dosage units flagged 14,795,350 – 82.5%[684]
- McKesson — Oxycodone dosage units flagged 3,501,970– 87.9%
  Hydrocodone dosage units flagged 3,261,250 – 87.4%[685]

Stated differently – this is what should have been blocked unless or until the suspicion of diversion was dispelled.[686] Had the Defendants applied Methodology A as their triggering system for suspicious orders, a substantial volume of opioid pills would never have been shipped to the City of Huntington or to Cabell County.[687]

387. Methodology B – Differs from A in that the trigger or cap is set in the same manner – a six month look back, however, rather than stop all future orders once the trigger is initiated by

[680] 5/26/21 Trial Tr. (Rafalski) at 87:14-88:11.

[681] 5/26/21 Trial Tr. (Rafalski) at 88:15-89:2.

[682] 5/26/21 Trial Tr. (Rafalski) at 89:3-9.

[683] 5/26 Trial Tr. (Rafalski) at 96:17-25.

[684] 5/26 Trial Tr. (Rafalski) at 97:1-3.

[685] 5/26 Trial Tr. (Rafalski) at 97:4-6.

[686] 5/26/21 Tr. (Rafalski) at 97:7-18.

[687] 5/26/21 Trial Tr. (Rafalski) at 97:13-18.

an order over the highest order in the last six months, future orders are shipped up to the cap and all orders over the cap or trigger are held or blocked.[688]

- ABDC — Oxycodone dosage units flagged 3,763,580 – 29.4%
  Hydrocodone dosage units flagged 5,616,380– 24.8%[689]
- Cardinal — Oxycodone dosage units flagged 11,325,200 – 65.9%
  Hydrocodone dosage units flagged 7,252,580 – 40.5%[690]
- McKesson — Oxycodone dosage units flagged 805,300– 20.2%
  Hydrocodone dosage units flagged 2,390,800 – 64%[691]

388. Methodology C – Twice trailing twelve-month looks back 12 months to identify an average number of pills distributed in either the state of West Virginia or nationally (depending on what data set was available). Each month the trigger is recalculated based upon the prior 12 months. This methodology would then calculate the trigger as double the prior twelve-month average.[692] *Stated differently – the following orders sent to Cabell and Huntington exceeded double each Defendant's average order over the prior 12 months:*

- ABDC — Oxycodone dosage units flagged 10,477,680 – 81.8%
  Hydrocodone dosage units flagged 18,877,140 – 83.4%[693]
- Cardinal — Oxycodone dosage units flagged 14,011,880 – 81.5%
  Hydrocodone dosage units flagged 16,593,780 – 92.6%[694]
- McKesson — Oxycodone dosage units flagged 2,405,620– 60.4%
  Hydrocodone dosage units flagged 2,362,420 – 63.3%[695]

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[688] 5/26/21 Trial Tr. (Rafalski) at 89:10-20.

[689] 5/26/21 Trial Tr. (Rafalski) at 98:3-6.

[690] 5/26/21 Trial Tr. (Rafalski) at 98:7-9.

[691] 5/26/21 Trial Tr. (Rafalski) at 98:10-11.

[692] 5/26/21 Trial Tr. (Rafalski) at 92:3-93:12.

[693] 5/26/21 Trial Tr. (Rafalski) at 98:16-19.

[694] 5/26/21 Trial Tr. (Rafalski) at 98:20-21.

[695] 5/26/21 Trial Tr. (Rafalski) at 98:22-24.

389. Methodology D used by all three Defendants, at varying points in time, functions similarly to Methodology C except that rather than doubling the prior twelve-month average order of pills, the trigger is set at triple or three times the prior twelve-month average.[696] *Stated differently – the following orders sent to Cabell and Huntington exceeded triple each Defendant's average order over the prior 12 months:*

- ABDC Oxycodone dosage units flagged 8,360,740 – 65.3%
  Hydrocodone dosage units flagged 15,701,930– 69.4%[697]
- Cardinal Oxycodone dosage units flagged 9,567,580 – 55.7%
  Hydrocodone dosage units flagged 14,957,360 – 83.5%[698]
- McKesson Oxycodone dosage units flagged 1,005,320– 25.2%
  Hydrocodone dosage units flagged 1,245,640 – 33.4%[699]

390. Methodology E- Maximum 8000 dosage units monthly, used by McKesson under the LDMP, set the trigger at 8,000 dosage units per customer per month.[700]

- ABDC Oxycodone dosage units flagged 10,446,280 – 81.5%
  Hydrocodone dosage units flagged 21,679,760– 95.8%[701]
- Cardinal Oxycodone dosage units flagged 13,274,080 – 77.2%
  Hydrocodone dosage units flagged 16,159,150 – 90.2%[702]
- McKesson Oxycodone dosage units flagged 2,098560– 52.7%
  Hydrocodone dosage units flagged 2,484,640 – 66.6%[703]

[696] 5/26/21 Trial Tr. (Rafalski) at 85:15-17; 93:13-21.

[697] 5/26/21 Trial Tr. (Rafalski) at 99:22-100:5.

[698] 5/26/21 Trial Tr. (Rafalski) at 100:6-12.

[699] 5/26/21 Trial Tr. (Rafalski) at 100:13-16.

[700] 5/26/21 Trial Tr. (Rafalski) at 93:22-94:19.

[701] 5/26/21 Trial Tr. (Rafalski) at 100:22-24.

[702] 5/26/21 Trial Tr. (Rafalski) at 100:25-101:2.

[703] 5/26/21 Trial Tr. (Rafalski) at 98:101:3-6.

391. Methodology F – Maximum daily dosage units – also called "pickers and packers" there is a maximum daily dosage unit order on a list in the cage or vault where the packers work and anything above the amount on the list in the vault is not shipped. In this case the amounts from the list of one of the Defendants was used for the calculations.[704]

- ABDC Oxycodone dosage units flagged 12,459,020 – 97.3%
  Hydrocodone dosage units flagged 22,582,020– 99.8%[705]
- Cardinal Oxycodone dosage units flagged 16,527,880 – 96.2%
  Hydrocodone dosage units flagged 17,688,100 – 98%[706]
- McKesson Oxycodone dosage units flagged 3,713,000– 93.2%
  Hydrocodone dosage units flagged 3,648,650 – 97.9%[707]

392. The foregoing demonstrates, *not* that 98% of any Defendant's orders necessarily would be diverted and could never be shipped, but that under each of a variety of flagging methodologies Defendants and others in their industry used, there were flagged orders containing millions of opioid pills that required Defendants to perform due diligence to dispel suspicion before they could ship these orders.[708]

393. Thus, not every flagged order would have to be reported to the DEA as suspicious. Only those that after sufficient due diligence, the suspicion could not be eliminated.[709]

394. The Court finds to a reasonable certainty, and for the reasons set forth below, that Defendants did not perform due diligence on these orders.

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[704] 5/26/21 Trial Tr. (Rafalski) at 94:20-95:21.

[705] 5/26/21 Trial Tr. (Rafalski) at 101:7-13.

[706] 5/26/21 Trial Tr. (Rafalski) at 101:14-17.

[707] 5/26/21 Trial Tr. (Rafalski) at 101:18-21.

[708] 5/26/21 Trial Tr. (Rafalski) at 76:2-20.

[709] 5/27/21 Trial Tr. (Rafalski) at 51:15-52:1.

395. Rafalski testified that there was insufficient evidence from each Defendant of due diligence conducted for triggered orders necessary to dispel the suspicion that diversion was likely to occur.[710]

396. This opinion is further supported by testimony of DEA's former Deputy Assistant Administrator of Diversion Control, Mr. Rannazzisi, that a distributor should consider the volume of opioids it sells to a customer or area relative to its population, Defendants neither weighed these factors, nor even totaled their shipments of opioids into a jurisdiction, in assessing whether orders were suspicious or diversion might be occurring.[711]

397. Rafalski also reviewed all suspicious orders each Defendant disclosed that it reported to the DEA as suspicious.[712]

398. AmerisourceBergen reported a total of 45 orders from Cabell County and Huntington to the DEA as suspicious.[713] ABDC pre-shipment reporting:[714]

2007 – 2
2008 – 4
2009 – 12
2010 – 5
2011 – 1
2012 – 4
2013 – 11

[710] 5/26/21 Trial Tr. (Rafalski) at 102:14-17.

[711] 6/8 Trial Tr. (Rannazzisi) at 186 ("what we asked them to do is look at your suspicious – your pharmacy population, your customer population, identify anomalies within that population, ordering patterns, and then do your due diligence and see why those anomalies exist"); 5/17 Trial Tr. (Mays) at 203, 205 (between 2007 and 2014 the diversion control program did not rely on populations); Prevoznik, 5/17/19 Depo at 974 (DEA had said that knowledge of a geographic area's problem with controlled substance abuse is a factor that should be taken into account by registrants); *see also See* 5/26/21 Trial Tr. (Rafalski) at 112 (orders the Defendants knew or should have known were suspicious were likely to be diverted into the illicit market).

[712] 5/26/21 Trial Tr. (Rafalski) at 102:18-24.

[713] 5/26/21 Trial Tr. (Rafalski) at 103:3-9.

[714] 5/26/21 Trial Tr. (Rafalski) at 103:3-21.

2014 – 6
2015 – 2018 – 0.

399. Cardinal Health suspicious order reporting for Cabell and Huntington[715]:

1996 to 2009 – 0
2010 – 1
2011 – 0
2012 – 15
2013 – 86
2014 – 5
2015 – 19
2016 – 34
2017 – 32.

400. McKesson suspicious order reporting for Cabell and Huntington[716]:

1996 to 2012 – 0
2013 – 5
2014 – 29
2015 – 20
2016 – 10
2017 – 2
2018 – 13

401. Rafalski's opinion is that AmerisourceBergen failed to maintain effective controls to prevent the diversion of prescription opioids into the illicit market in the City of Huntington or Cabell County.[717]

402. Rafalski's opinion is that Cardinal Health failed to maintain effective controls to prevent the diversion of prescription opioids into the illicit market in the City of Huntington or Cabell County.[718]

[715] 5/26/21 Trial Tr. (Rafalski) at 104:14 – 105:16.

[716] 5/26/21 Trial Tr. (Rafalski) at 105:17-106:1.

[717] 5/26/21 Trial Tr. (Rafalski) at 107:3-10 and 110:5-12.

[718] 5/26/21 Trial Tr. (Rafalski) at 108:3-14.

403. Rafalski's opinion is that McKesson failed to maintain effective controls to prevent the diversion of prescription opioids into the illicit market in the City of Huntington or Cabell County.[719]

404. Rafalski's opinion is that AmerisourceBergen, Cardinal and McKesson did not design and operate effective systems to identify, block and report suspicious orders arising in the City of Huntington and Cabell County.[720] And each Defendant's failures were systemic or widespread.[721] The systemic failures were a substantial factor in the diversion of prescription opioids into the illicit market in the City of Huntington and Cabell County.[722] The orders Defendants knew or should have known were suspicious were likely to be diverted into the illicit market in the City of Huntington and Cabell County.[723]

405. Rafalski reviewed comments dating back as far as 1987 from the DEA indicating that shipping suspicious orders then reporting them to the DEA as suspicious did not factor in public safety.[724]

406. Maintaining records evidencing due diligence conducted is necessary for the maintenance of effective controls against diversion.[725]

407. This is especially so after the 2005 and 2006 Distributor Briefings and after each Defendant was subject to administrative action in 2007 and 2008.[726]

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[719] 5/26/21 Trial Tr. (Rafalski) at 108:15-24.

[720] 5/26/21 Trial Tr. (Rafalski) at 108:25-109:7.

[721] 5/26/21 Trial Tr. (Rafalski) at 109:8-18.

[722] 5/26/21 Trial Tr. (Rafalski) at 111:19-112:2.

[723] 5/26/21 Trial Tr. (Rafalski) at 112:22-113:3; 214:10-12.

[724] 5/26/21 Trial Tr. (Rafalski) at 260:25-261:16.

[725] 5/26/21 Trial Tr. (Rafalski) at 270:1-12.

[726] 5/27/21 Trial Tr. (Rafalski) at 17-21.

408. The Court finds that each Defendant's conduct was unreasonable in failing to maintain adequate and effective controls against diversion and causing suspicious orders containing tens of millions of opioid dosage units to be shipped to Cabell and Huntington, with population of fewer than 100,000 people, and the surrounding region.

III. Defendants Substantially and Foreseeably Contributed to the Opioid Epidemic in Cabell County and the City of Huntington.

409. The Court finds that Defendants' failure to maintain adequate and effective controls of the prescription opioid drugs they distributed was a substantial factor in bringing about the public nuisance harms of the opioid epidemic in Cabell and Huntington. The Court further finds that these harms were and are the foreseeable and foreseen result of Defendants' unreasonable conduct.

A. Defendants Substantially Contributed to the Opioid Epidemic Harms in Cabell and Huntington.

1. Substantial Contribution to Diversion in Cabell and Huntington

410. The Court finds that Defendants' failure to maintain adequate and effective controls against diversion caused the diversion of prescription opioid pills they shipped to Cabell County, the City of Huntington, and the surrounding region.

411. The core purpose of the CSA "was to prevent diversion" of controlled substances by creating a "closed system" of distribution in which all parties to the supply chain must be registered with the federal government.[727]

[727] 5/5/21 Trial Tr. (Courtwright) at 43.

412. This "Closed System of Distribution overall is just a system of accountability to ensure that nothing is leaving the system and going into the illicit marketplace."[728]

413. Mr. Rannazzisi testified that any breach of this closed system results in the diversion of controlled substances into the illicit market:

> If there's a breach in the integrity of the closed system, drugs are funneled out of that supply chain into the illicit market. It's a total – it's a breakdown. A breakdown of the system will cause diversion. And that – it's as simple as that. It doesn't get any more simple.[729]

414. Mr. Rannazzisi further testified that Defendants' and other distributors' "Suspicious Order Monitoring Program is your tool" to prevent diversion.[730]

415. The DEA viewed Defendants and other distributors as a "choke point" to stop the flow of diverted opioid pills from internet pharmacies.[731]

416. The DEA also recognizes that distributors' setting of arbitrary thresholds for suspicious order monitoring "could actually create oversupplies[,]" and that "increases in availability" of controlled substances "could have the unintended consequence of increasing diversion and abuse."[732]

417. The DEA also recognizes that a CSA registrant's "failure to comply [with federal law] enables more diversion."[733]

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[728] 6/7/21 Trial Tr. (Rannazzisi) at 175.

[729] 6/7/21 Trial Tr. (Rannazzisi) at 180-81.

[730] 6/7/21 Trial Tr. (Rannazzisi) at 180.

[731] 6/7/21 Trial Tr. (Rannazzisi) at 184.

[732] Strait, 5/31/19 30(b)(6) Dep. at 34-35, 41-42.

[733] Prevoznik, 4/18/19 30(b)(6) Dep. at 642.

418. Plaintiffs' diversion investigation expert, Mr. Rafalski, testified in reference to distributors and other DEA registrants that, "[i]f you don't dispel the suspicion of that order and of future orders, if you hadn't removed that suspicion of diversion or dispelled it, more likely than not, that's what would occur[.]"[734]

419. Plaintiffs' epidemiology and Opioid Use Disorder ("OUD") expert, Dr. Keyes, testified that an increased volume of prescription opioids, such as that brought about by a failure to maintain adequate or effective controls, "is a substantial contributing factor" to diversion into the illicit market.[735]

420. The primary methods of drug diversion in West Virginia and the Appalachian region during the first decade of this century were the "illegal sale and distribution by healthcare professionals," as well as "employee theft, forged prescription, and the internet."[736]

421. Huntington's former Chief of Police, William Holbrook testified as to his department's observation of illegal sale and distribution and diversion as follows:

> Often times, especially with diversion, an investigation would start with a call to a tip line, a pharmacy calling, a traffic stop and finding prescription pills in somebody's possession and they not have a legitimate prescription, or they would have one and you would find multiple pharmacies or doctors they had been to. So you would see some evidence where it looked like maybe a pharmacist or a doctor potentially was, again, distributing, prescription drugs, opioids irresponsibly.[737]

422. Defendant McKesson Corporation states in its operation manual that "[i]t is extremely important that McKesson employees comply fully with the regulations and . . .

[734] 5/26/21 Trial Tr. (Rafalski) at 104.

[735] 6/15/21 Trial Tr. (Keyes) at 31-32.

[736] 6/10/21 Trial Tr. (Smith) at 221.

[737] 6/17/21 Trial Tr. (Holbrook) at 207-08.

guidelines" on diversion control because it recognizes that this is "extremely important" in order to "prevent the diversion of controlled substances."[738]

423. McKesson also agrees that "if you don't follow those laws" creating a closed system of controlled substances distribution, then "diversion into the illicit market . . . can happen[,]"and that, "[u]sing common sense and basic logic, you could assume the more pills that are out there, the more potential for diversion there could be."[739]

424. Defendants' pain management standard of care expert, Dr. Timothy Deer, similarly recognized that a physician prescribing "outside the standard of care is not diverting pills, but their improper prescribing could cause diversion by someone else."[740]

2. Diversion Occurring Across State and Local Boundaries

425. The Court finds that the diversion of the prescription opioid pills Defendants shipped to Cabell and Huntington that occurred was not geographically contained within the County and City's boundaries, but rather occurred across these boundaries to and from other locations within and beyond the surrounding region.

426. Mr. Rannazzisi, testified that while he was with the DEA he understood that:

> 'Oxy Express' was a term given to people that go down to Florida to visit pill mills. They might go three, four, five at a time and then load up either by car, or by bus, or even by plane and take the drugs back to where they came from. But Oxy Express originally was the I-75 Corridor going up into – going up through Georgia, past Georgia, and then spreading out into the Midwest.[741]

427. Mr. Rannazzisi further testified that the Oxy Express operated as follows: "You go down, you visit multiple pill mills, multiple prescription mills. You get your drug from pharmacies

[738] Hartle, 7/31/18 30(b)(6) Dep. at 108.

[739] Hartle, 7/31/18 30(b)(6) Dep. at 58-59, 268.

[740] 7/7/21 Trial Tr. (Deer) at 161.

[741] 6/8/21 Trial Tr. (Rannazzisi) at 24.

in the area and you take them back to wherever you came from. Some of these people just got the prescriptions[,] loaded up and then headed back north to wherever they came from and had the prescriptions actually filled at their local pharmacies."[742]

428. Mr. Rannazzisi specifically tied this interstate diversion of prescription opioid pills to Defendants' distribution activity, describing large-scale diversion occurring through internet pharmacies and spreading "across the country" and "across all of the states[,]"[743] and testifying that "Amerisource, McKesson, and Cardinal had a big role in [supplying] those internet pharmacies."[744]

429. The Appalachia High Intensity Drug Trafficking Area ("HIDTA") connected cross-border diversion of prescription opioid pills to the Appalachian region:

> The Appalachian region, obviously, was one of the hardest hit regions in the country for opioid abuse. We had a great amount of citizens traveling out of state to obtain prescription medication, to south Florida most specifically, and other states as well, because Kentucky had a very robust prescription monitoring program.[745]

430. Appalachia HIDTA connected cross-border diversion of prescription opioid pills from Florida to West Virginia and surrounding states,[746] and specifically to Huntington: "Q. In your role at HIDTA –at HIDTA, you've also reported on the trend of pills from Florida being diverted into Huntington. Is that correct? A. That's correct."[747]

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[742] 6/8/21 Trial Tr. (Rannazzisi) at 24-25.

[743] 6/7/21 Trial Tr. (Rannazzisi) at 191-92.

[744] 6/7/21 Trial Tr. (Rannazzisi) at 185.

[745] Brown, 5/17/20 30(b)(6) Dep. at 18.

[746] Brown, 5/17/20 30(b)(6) Dep. at 249-50

[747] Brown, 5/17/20 30(b)(6) Dep. at 254-55.

431. Defendant McKesson Corporation's former Vice President of Regulatory Affairs and Compliance, Nathan Hartle, testified that he agrees that "[d]rugs don't just – because you sell it to one particular pharmacy doesn't – in one particular town doesn't mean that drug is staying in that town,"[748] that "I'm aware of . . . how drugs move and migrate[,]"[749] and that "I agree that diversion migrates."[750]

432. McKesson's current Vice President of Regulatory Affairs, Gary Boggs, testified that he agrees that: "[D]rugs that find their way into the illegal distribution system in a given community will not remain in that community; they will – some of those drugs will migrate to adjacent communities and even different states."[751]

433. Mr. Boggs also prepared a PowerPoint presentation titled "Drug Diversion Migration out of Florida," which he testified was meant to depict "the criminal schemes of pill mills in Florida, and where those complicit in the criminal scheme . . . would take those [drugs] . . . out of Florida and into other locations throughout the United States."[752]

434. ABDC Director of Diversion Control and Security, Edward Hazewski, testified that "it was generally discussed information in the industry" that "people would travel to places like Florida and bring pills back into other areas like West Virginia and Ohio."[753]

[748] Hartle, 8/1/18 Dep. at 319.

[749] Hartle, 8/1/18 Dep. at 320.

[750] Hartle, 8/1/18 Dep. at 323.

[751] Boggs, 1/17/19 Dep. at 259-60.

[752] Boggs, 1/17/19 Dep. at 261.

[753] Hazewski, 10/25/18 Dep. at 71-72.

435. Mr. Hazewski also testified that he agrees that "someone who has a legitimate medical need for a prescription probably wouldn't be driving out of the area to get their prescription."[754]

436. ABDC's former Vice President of Sales for West Virginia, Lisa Mash, testified that she was familiar from company trainings and other sources with the term "Oxy Express" and its reference to pill migration from Florida and through West Virginia.[755] She also testified that ABDC trained its employees to be aware at pharmacy customer stores of "license plates from various states, more than would constitute a local customer base."[756]

437. ABDC's Senior Vice President of Corporate Security and Regulatory Affairs, Chris Zimmerman, similarly testified that the "*Pillbillies*" song parody email he circulated among ABDC employees contained an implicit recognition that there was opioid diversion or pill migration between Florida and West Virginia: "Q. This is an implicit recognition that there was pill migration from Florida up into Mountaineer land? A. Somebody wrote a parody that included that, yes."[757]

438. Mr. Zimmerman also acknowledged use of the terms "Blue Highway" and "Oxy Express" to refer to migration of opioid pills "up from Florida."[758]

[754] Hazewski, 10/25/18 Dep. at 72-73.

[755] Mash, 7/28/20 Dep. at 81-82.

[756] Mash, 7/28/20 Dep. at 118.

[757] 5/13/21 Trial Tr. (Zimmerman) at 90.

[758] 5/13/21 Trial Tr. (Zimmerman) at 90.

3. Substantial Contribution to Opioid Epidemic Harms in Cabell and Huntington

439. The Court finds that diversion of the prescription opioid pills Defendants shipped to Cabell and Huntington substantially contributed to the opioid epidemic's public health and safety harms afflicting the County and City.

440. The DEA's former Deputy Assistant Administrator for the Office of Diversion Control, Mr. Rannazzisi, testified that when there is a breach of the closed system of controlled substances distribution that results in diversion, what occurs is:

> The market being flooded, the illicit marketplace being flooded with opioids, benzodiazepines, mild stimulants, people becoming addicted, people overdosing, police officers required, being required to carry naloxone, which is not part of their duties up until a few years ago when we had to start carrying it because the overdoses were outrageous, and of course . . . losing loved ones.[759]

441. Plaintiffs' epidemiology and OUD expert, Dr. Keyes, testified that there is a "causal association between the supply of prescription opioids in Cabell and Huntington and the increase in opioid-related harms[,]"[760] that "the opioid supply and oversupply is causally related to the opioid-related harms[,]"[761] and that "there is a causal relationship between [opioid] volume and harm."[762]

442. Dr. Keyes further testified that opioid oversupply causes opioid-related harms is consistent with the consensus statement of the Association for Schools of Public Health, which states in part that:

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[759] 6/7/21 Trial Tr. (Rannazzisi) at 180-81.

[760] 6/11/21 Trial Tr. (Keyes) at 204.

[761] 6/11/21 Trial Tr. (Keyes) at 217.

[762] 6/15/21 Trial Tr. (Keyes) at 31.

> The tremendous expansion of the supply of powerful high potency, as well as long-acting prescription opioids led to scaled increases in prescription opioid dependence.[763]

443. Plaintiffs' epidemiology and drug overdose expert, Dr. Gordon Smith, testified that the numbers of drug overdose deaths per year in West Virginia were constant and "completely flat" between 1979 and 2000, but that after the introduction of prescription opioids around 2000, "then we saw the exponential growth, yes."[764]

444. Plaintiffs' history of opiate use and abuse and drug policy expert, Dr. Courtwright, testified that "supply and exposure were both critical" to past opioid epidemics, where "opiates were widely available not only from physicians, but in patent medicines which often contained opium and morphine[,]"[765] as a result of which "the per capita consumption of medicinal opiates in the United States tripled between 1870 and 1890, which was right in the heart of that first epidemic."[766]

445. McKesson's Vice President of Regulatory Affairs and Compliance, Mr. Boggs, testified that "there is a correlation between diversion and – and associated problems with diversion[,]" and that he agrees that "the greater the amount of diversion, the greater the likelihood of ensuing harm, such as addiction and death."[767]

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[763] 6/11/21 Trial Tr. (Keyes) at 171.

[764] 6/10/21 Trial Tr. (Smith) at 216.

[765] 5/5/21 Trial Tr. (Courtwright) at 28.

[766] 5/5/21 Trial Tr. (Courtwright) at 29.

[767] Boggs, 1/17/19 Dep. at 134-35.

446. Defendants' substance use disorder care systems expert, Stephanie W. Colston, testified that "oversupply of prescription opioids is not *the* causal factor of the opioid epidemic, but is only *a* causal factor."[768]

a. Opioid Epidemic Harms—*Overdose Deaths*

447. The Court finds that diversion of the prescription opioid pills Defendants shipped to Cabell and Huntington substantially contributed to the sharp increase in opioid overdose deaths in the County and City.

448. Plaintiffs' epidemiology and drug overdose expert, Dr. Smith, testified that prescription opioid poisoning death was so rare before the year 2000 that he had to rely on West Virginia-wide data on drug poisonings as a whole to assess its occurrence: "[T]here were so few overdose deaths from opioids that I had to go to the next level of grouping what they do, which was all accidental overdoses of which the drug poisonings are part of."[769]

449. Dr. Smith testified that the pre-2000 data showed that the number of drug-poisoning deaths in West Virginia was low and stable between 1979 and 1999, with an average of fewer than 76 drug-poisoning deaths per year Statewide: "This broad category which I showed earlier includes the drug poisoning and includes specifically opioid overdoses was very relatively flat until 2000. And then, as you can see here, the numbers just – the rates increased very dramatically."[770]

450. In 2001, the first year for which Dr. Smith was able to obtain drug-specific poisoning death data for Cabell County, this data showed that there were 16 drug-poisoning deaths in Cabell County alone, of which the vast majority—14 of the 16—were opioid related.[771]

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[768] 7/12/21 Trial. Tr. (Colston) at 154.

[769] 6/10 /21Trial Tr. (Smith) at 118, 125-26.

[770] 6/10/21 Trial Tr. (Smith) at 128-30.

[771] 6/10/21 Trial Tr. (Smith) at 133.

451. For the years from 2001 to 2018, there was a total of 1,002 opioid-related deaths in Cabell County, representing almost 90% of all drug-poisoning deaths in the county.[772]

452. While the absolute numbers of opioid-related poisoning deaths in soared in Cabell County, so too did the rate of fatal overdoses, which increased from 16.6 to 213.9 per 100,000 people between 2001 and 2017.[773] This represents an increase of almost 1,200%.

453. Dr. Smith testified that "there is an ongoing role of prescription opioids as a cause of drug overdose mortality in the Cabell and Huntington community" because "there is an increase and there is a very continue presence of illicit – of both – of opioids and prescription opioids over this period of time."[774]

454. Dr. Smith also testified that a study of 295 overdose deaths in 2008 in West Virginia as a whole showed that pharmaceutical diversion was associated with 186 (63%) of the deaths, while another 63 (21.4%) showed evidence of doctor-shopping.[775]

455. Dr. Smith further testified that this study showed that opioid analgesics were taken by 275 of the 295 decedents (93.2%), but that less than half of those decedents (122 of 275, or 44.4%) had ever been prescribed opioids.[776]

456. Dr. Smith thus concluded as follows:

> My conclusion from reading the literature, looking at my own reports and what I found, was that there was a very, very conclusive evidence that prescription drugs and prescription opioids in particular play – continue to play a very important role in the drug overdose deaths in West Virginia.[777]

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[772] 6/10/21 Trial Tr. (Smith) at 134.

[773] 6/10/21 Trial Tr. (Smith) at 139-40.

[774] 6/10/21 Trial Tr. (Smith) at 141.

[775] 6/10/21 Trial Tr. (Smith) at 145-46.

[776] 6/10/21 Trial Tr. (Smith) at 147.

[777] 6/10/21 Trial Tr. (Smith) at 153.

457. Plaintiffs' epidemiology and OUD expert, Dr. Keyes, also testified based on her review of epidemiological literature that "overdose" and "death" were among the harms caused by exposure to supplies of prescription opioid pills in Cabell and Huntington,[778] "opioid supply and oversupply is causally related" and is a "substantial factor" in opioid "overdoses" and "mortality" in Cabell and Huntington.[779]

458. West Virginia's former Bureau of Public Health Commissioner, Dr. Gupta, testified by reading from a report he commissioned as Public Health Commissioner that: "The number one cause of drug overdose deaths was associated opiates, making West Virginia number one in the nation."[780]

459. Defendant McKesson Corporation succinctly acknowledges this point: "The volume of opioids in the market and diversion is related to opioid deaths, certainly."[781]

b. Opioid Epidemic Harms—*Opioid Use Disorder*

460. The Court finds that diversion of the prescription opioid pills Defendants shipped to Cabell and Huntington substantially contributed to the sharply increased incidence of Opioid Use Disorder in the County and City.

461. Plaintiffs' epidemiology and OUD expert, Dr. Keyes, testified that the consensus statement of the Association for Schools of Public Health recognized that the "tremendous expansion of the supply of powerful high potency, as well as long acting prescription opioids led

[778] 6/11/21 Trial Tr. (Keyes) at 182.

[779] 6/11/21 Trial Tr. (Keyes) at 217-18.

[780] 5/6/21 Trial Tr. (Gupta) at 149.

[781] Hartle, 7/31/18 30(b)(6) Dep. at 294.

to scaled increases in prescription opioid dependence[,]" and that "Opioid Use Disorder is caused by repeated exposure to opioids."[782]

462. Dr. Keyes then testified as to her own expert opinion as follows:

> I reviewed the literature and compared them to all of the key factors that we look at and they all point in one direction and that is that increased exposure to the supply of prescription opioids caused harms in Cabell and Huntington[,][783]

and that, among these harms was "Opioid Use Disorder. I would also list diversion and non-medical use."[784]

463. Dr. Keyes explained that various of the Bradford Hill factors for assessing causal relationships[785] supported her opinion that increased exposure to the supply of prescription opioids caused increased incidence of OUD in Cabell and Huntington.

464. First, Dr. Keyes testified that there is a "dose-response" relationship between opioid supply and exposure on the one hand and development of OUD on the other:

> Duration can be considered a measure of dose because, as the duration goes on, you're exposed to a higher dose. This has been shown repeatedly in the epidemiological literature with regard to Opioid Use Disorder, both among people who are taking a prescription and among people who are using prescription opioids non-medically.[786]

465. She identified a study (Edlund) showing a direct relationship between increased dose and duration of opioid use and higher incidence of OUD, including that people taking high-

[782] 6/11/21 Trial Tr. (Keyes) at 171.

[783] 6/11/21 Trial Tr. (Keyes) at 182.

[784] 6/11/21 Trial Tr. (Keyes) at 182.

[785] 6/11/21 Trial. Tr. (Keyes) at 163.

[786] 6/11/21 Trial Tr. (Keyes) at 185.

dosage opioids for over 90 days were 122 times more likely to develop OUD, which she described as an "extraordinarily strong" association.[787]

466. She identified another study (Ghertner) showing that each increase in the distribution of prescription opioids by county was associated with a 4% increase in opioid-related hospitalizations.[788]

467. Second, Dr. Keyes testified that the Bradford Hill factor of "temporality" supports her opinion that prescription opioid supply caused OUD in Cabell and Huntington: "So for temporal relationships what we're really looking for is people who didn't have a history of [OUD] before they were prescribed opioids, for example . . . . And we want to establish that the cause precedes the effect. And that's well documented in the epidemiological literature."[789]

468. Third, Dr. Keyes testified that the "strength of association" between prescription opioid supply and occurrence of OUD further supports her opinion: "And, generally, I think there's consensus in my field that the strongest risk factor for [OUD] is prescription opioid exposure."[790]

469. Fourth, Dr. Keyes testified that the "biological plausibility" of the causal relationship between prescription opioid supply and OUD is reflected in the medical literature.[791]

470. Fifth, and finally, Dr. Keyes testified that the absence of alternative explanations for causation of OUD supports her opinion that supply is a substantial contributing factor:

> Certainly one that's been discussed a lot is economic conditions. . . . And what's been demonstrated in well-done studies . . . [is] that economic conditions really,

[787] 6/11/21 Trial Tr. (Keyes) at 186-89.

[788] 6/11/21 Trial Tr. (Keyes) at 192.

[789] 6/11/21 Trial Tr. (Keyes) at 193.

[790] 6/11/21 Trial Tr. (Keyes) at 194.

[791] 6/11/21 Trial Tr. (Keyes) at 195.

> when you analyze the data in a rigorous way, play a relatively small role in the opioid-related harms that we've seen in the United States over the last 15 years.[792]

471. Dr. Keyes further identified 8,252 OUD cases in Cabell and Huntington of which she testified that 7,109 of these cases are attributable to prescription opioids.[793]

472. Dr. Keyes thus concluded that "the opioid supply and oversupply is causally related to the opioid-related harms" and agreed that this includes "being a substantial factor in [OUD] in Huntington/Cabell County."[794]

473. The testimony of fact witnesses in law enforcement underscores the Court's finding that prescription opioid supply and oversupply caused OUD in Cabell and Huntington.

474. The DEA's former Deputy Assistant Administrator for the Office of Diversion Control, Mr. Rannazzisi, testified that when there is a breach of the closed system of controlled substances distribution that results in diversion, one of the harms that results is "people becoming addicted, people overdosing[.]"[795]

475. Former Huntington Chief of Police, Mr. Holbrook, testified that "the prevalence of drugs depends on demand, supply and demand. And there was an outrageously strong appetite, demand for drugs in Huntington. And we had an addicted population, unfortunately."[796]

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[792] 6/11/21 Trial Tr. (Keyes) at 195-96.

[793] 6/14/21 Trial Tr. (Keyes) at 175.

[794] 6/11/21 Trial Tr. (Keyes) at 217-18.

[795] 6/7/21 Trial Tr. (Rannazzisi) at 180-81.

[796] 6/17/21 Trial Tr. (Holbrook) at 196.

c. Opioid Epidemic Harms—*Heroin/Fentanyl Use*

476. The Court finds that diversion of the prescription opioid pills Defendants shipped to Cabell and Huntington substantially contributed to the transition, starting in the early 2010s, of opioid-addicted persons in the County and City from using pills to also using heroin and fentanyl.

477. Plaintiffs' neuroscience, addiction, and pain treatment expert, Dr. Corey Waller, testified that prescription opioid pills and heroin interact identically with the human brain: "Q. Does the brain know the difference between whether or not this is hydrocodone, oxycodone, or heroin? A. It has no idea."[797]

478. This is because each of these drugs causes the brain's mu-receptor to receive the same neurotransmission, so that "the brain doesn't know what drug you just gave it. It just knows the action that it has."[798]

479. Based on this identical interaction with the brain, Dr. Waller testified that the relationship between prescription opioid and heroin use is even stronger than that of a gateway:

> I don't use a gateway. It's no different. I mean, for some people it doesn't – it's no different for them because when they take oxycodone or hydrocodone, for them if they have that same change in the brain chemistry, they might as well have taken the other. It doesn't matter. It's an opioid that binds in the brain disproportionately releasing this dopamine and causing the same behavioral phenomenon with this need to search for dopamine.[799]

480. Dr. Waller thus concluded based on both his expertise in the science and his experience as a clinician that there is a "clear connection" between prescription opioid abuse and heroin abuse.[800]

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[797] 5/4/21 Trial Tr. (Waller) at 71.

[798] 5/4/21 Trial Tr. (Waller) at 71-72.

[799] 5/4/21 Trial Tr. (Waller) at 71.

[800] 5/4/21 Trial Tr. (Waller) at 204.

481. Plaintiffs' epidemiology and OUD expert, Dr. Keyes, likewise testified that "there is a causal connection between prescription opioids and heroin."[801]

482. Dr. Keyes referenced the consensus statement of the Association for Schools of Public Health, which states that "the tremendous expansion of the supply of powerful high potency, as well as long-acting prescription opioids" led to both "scaled increases in prescription opioid dependence" and the "transition of many to illicit opioids, including fentanyl and its analogs which have subsequently driven exponential increases in overdoses."[802]

483. Dr. Keyes testified that substantial epidemiological literature supports her opinion that prescription opioid supply and use causes heroin use. This includes a study (Cicero) showing that since the expansion of opioid prescribing and distribution in the 1990s, most people (70-80%) who have used heroin started with a prescription opioid first.[803]

484. Dr. Keyes further described a study of Veterans Administration data following over 3,000 U.S. military veterans between the ages of 40 and 60, and finding that those who used prescription opioids were more than five times as likely to use heroin.[804]

485. Dr. Keyes also testified as to how the Bradford Hill factors of biological plausibility ("They have similar pharmacological properties.") and temporality ("80 percent of people used prescription opioids before they used heroin . . . .") support her opinion that prescription opioid use causes heroin use.[805]

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[801] 6/11/21 Trial Tr. (Keyes) at 169.

[802] 6/11/21 Trial Tr. (Keyes) at 171.

[803] 6/11/21 Trial Tr. (Keyes) at 173-74.

[804] 6/11/21 Trial Tr. (Keyes) at 176-77.

[805] 6/11/21 Trial Tr. (Keyes) at 180, 193.

486. Dr. Keyes thus testified in conclusion that "an increase in the volume of prescription opioids causally leads to an increase in heroin use[,]"[806] so that Defendants' distribution of 80 million prescription opioid pills into Cabell and Huntington is a substantial factor in the evolution of the opioid epidemic there from one of prescription use and abuse to one intertwined with heroin and fentanyl abuse.[807]

487. Plaintiffs' epidemiology and drug overdose expert, Dr. Smith, testified that "up until 2001, heroin was not much of a problem[,]" but that after there was a "very dramatic rise in prescription opioids[,]" we then "really started to see the increase [in heroin] beginning in 2011."[808]

488. Plaintiffs' health economist expert, Dr. Thomas McGuire, testified with reference to a White House Council of Economic Advisors statement that prescription opioids "have high potential for abuse which can lead users to substitute more lethal opioids without accepted medical uses such as heroin or illicitly produced fentanyl."[809]

489. Plaintiffs' epidemiology and opioid abatement intervention expert, Dr. Caleb Alexander, testified that "prescription opioids and heroin and fentanyl are two sides of the same coin. They have the same effects on the body. They produce the same type of physical dependency and the same risks of addiction."[810]

490. Dr. Alexander thus concluded that, "while the [Cabell and Huntington] community in the early stages of the epidemic was predominantly flooded with prescription opioids and while

[806] 6/15/21 Trial Tr. (Keyes) at 31.

[807] 6/15/21 Trial Tr. (Keyes) at 27-29.

[808] 6/10/21 Trial Tr. (Smith) at 136.

[809] 6/17/21 Trial Tr. (McGuire) at 75.

[810] 6/28/21 Trial Tr. (Alexander) at 26-27.

now heroin and illicit fentanyl have taken on heightened concern, I would characterized the epidemic as an opioid epidemic, not one of one particular type of opioid or another."[811]

491. West Virginia's former Bureau of Public Health Commissioner, Dr. Gupta, testified that his office's Social Autopsy Report showed overdose victims filling prescriptions 12 months before, but not ingesting opioid pills within 30 days of the overdose, meaning "they quit filling prescriptions . . . . They died of heroin and fentanyl. That is a very clear pathway from prescription drugs to fentanyl and heroin."[812]

492. An HIV Epidemiologic Profile of West Virginia commissioned by Dr. Gupta likewise concludes that: "The abuse of prescription medication has been a serious issue in the State for a while. But now, users are turning to cheaper and more potent opioids – heroin and fentanyl. Nationwide, among hew heroin users, 75% report having abused prescription opioids before using heroin."[813]

493. Scott Lemley of the City of Huntington Mayor's Office of Drug Control Policy testified that his Office's community engagement showed that people "started out on a prescription pill and then they moved over to heroin because that was what they could get, that's what they could find, that's what was affordable to them because eventually [pills] became more scarce."[814]

494. Former Huntington Chief of Police, Mr. Holbrook, testified that with respect to the opioids, we, we knew that as prices would go up . . . that folks would not be able to pay that and

[811] 6/28/21 Trial Tr. (Alexander) at 27.

[812] 5/5/21 Trial Tr. (Gupta) at 168-69.

[813] P-41901_00051 (HIV Epidemiologic Profile West Virginia).

[814] 5/21/21 Trial Tr. (Lemley) at 142.

they would turn to cheaper alternatives. And there was great risk with some of those cheaper alternatives, heroin being one of them."[815]

495. The Huntington Police Department's 2012 Threat Assessment and Drug Strategy, commissioned by Chief Holbrook, similarly concluded that:

> Heroin has also become an emerging threat to our community due to the availability and affordability of the drug. Many people who have developed opiate addictions due to abuse of prescription medication turn to heroin due to the lower price: $30-80 for a prescription pill compared to $20-25 for a dosage unit of heroin.[816]

496. Appalachia HIDTA likewise provided testimony that "availability[] is the main driving factor in switching to heroin. Once the availability of the opioids became less prevalent due to price and availability, many of those users switched over to heroin and fentanyl and other derivatives of synthetic opioids."[817]

497. Defendant ABDC's Senior Vice President of Diversion Control, David May, testified that when a person is cut off from prescribed opioids, he can "on his own go out into the streets and find a substitute for those drugs that he was taking[,]" so that " in the realm of possibilities, yes, that can – that can absolutely happen."[818]

498. ABDC's Senior Vice President of Corporate Security and Regulatory Affairs, Mr. Zimmerman, testified that "I've heard OxyContin referred to as hillbilly heroin, yes."[819]

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[815] 6/17/21 Trial Tr. (Holbrook) at 219.

[816] P-41374 (2012 HPD Threat Assessment and Drug Strategy).

[817] Brown, 5/17/20 30(b)(6) Dep. at 273.

[818] 5/14/21 Trial Tr. (May) at 30-31.

[819] 5/13/21 Trial Tr. (Zimmerman) at 88-89.

499. McKesson's former Vice President of Regulatory Affairs and Compliance, Mr. Hartle, testified that he agreed that "narcotic painkiller abuse, opioid abuse, [can be] a gateway to heroin use."[820]

500. Defendants' pain management and prescription opioids risks and benefits expert, Dr. Christopher Gilligan, testified that he does not dispute studies finding "an overall association of both non-medical and medical use of opioid analgesics with transition to heroin use with particular concerns about early non-medical use."[821]

501. Dr. Gilligan further testified that:

> I think if there are a large number of medications prescribed in any area, there will be some of them that will be diverted, misused, abused. And so, that there would be . . . some instances where that would lead to someone initiating heroin. I think that would be statistically likely in any area with a large number of opioid pain medications that were prescribed.[822]

502. Dr. Gilligan thus concluded that "there's a direct relationship that includes the misuse and abuse of prescription opioids, along with many other predisposing factors, that then does relate to initiation of heroin."[823]

503. Defendants' health economics expert, Dr. Kevin Murphy, testified with respect to the relationship between non-medical use of prescription opioids and later use of heroin that "if you focus on abuse of prescription opioids and abuse of heroin, they're probably closer to substitutes . . . like Coke or Pepsi."[824]

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[820] Hartle, 8/1/18 Dep. at 37.

[821] 7/2/21 Trial Tr. (Gilligan) at 156.

[822] 7/2/21Trial Tr. (Gilligan) at 159.

[823] 7/2/21 Trial Tr. (Gilligan) at 161-62.

[824] 7/8/21 Trial Tr. (Murphy) at 147.

504. The evidence thus strongly demonstrates that diversion of the prescription opioid pills Defendants shipped to Cabell and Huntington substantially contributed to the transition, starting in the early 2010s, of opioid-addicted persons in the County and City from using pills to also using heroin and fentanyl.

d. Opioid Epidemic Harms—*Infectious Diseases*

505. The Court finds that diversion of the prescription opioid pills Defendants shipped to Cabell and Huntington substantially contributed to an increased rate of infectious diseases, including HIV, Hepatitis B and C, and Endocarditis, in the County and City.

506. Plaintiffs' infectious diseases expert, Dr. Judith Feinberg, testified as to how and why the opioid epidemic's increase in injection drug use has been accompanied by increases in infectious diseases in Cabell and Huntington and elsewhere:

> [T]he vast majority of the infections that people get who are injecting opioids are blood-borne infections. You are injecting material that isn't sterile and that has been prepared in unsterile equipment and injected, you know, if it's a shared syringe with no an unsterile syringe through skin that is typically not clean.
>
> So you've got the opportunity to directly introduce organisms into the blood. And, of course, then it's easy for them to get anywhere in the body.
>
> . . . [T]he infections that cause the greatest morbidity and mortality are the ones that enter the blood.[825]

507. Dr. Feinberg testified with respect to HIV that "for people who inject drugs, every time you inject, there's a 1 in 160 chance of acquiring HIV[,]" and that "the more times you inject, . . . that risk accumulates."[826] This makes injection drug use the second most common way to contract HIV.[827]

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[825] 6/17/21 Trial Tr. (Feinberg) at 112.

[826] 6/17/21 Trial Tr. (Feinberg) at 115.

[827] 6/17/21 Trial Tr. (Feinberg) at 115.

508. This causal relationship is borne out by data from Cabell County, which shows that there were 69 new HIV cases in 2019, of which 90% were among people who inject drugs.[828]

509. Dr. Feinberg testified that Hepatitis C is even more contagious than HIV, with approximately 40% of injection drug users contracting Hepatitis C in their first year of use.[829]

510. As a result, West Virginia has for the past two decades been among the top two or three states for rate of Hepatitis C infection,[830] while the rate of Hepatitis C infection in Cabell County is far higher still, reaching a rate of 10.3 cases per 100,000 people, which was more than double the already-high Statewide rate of infection (5.1 per 100,000).[831]

511. Dr. Feinberg testified that Hepatitis B, too, is highly associated with injection drug use and that, as a result, West Virginia has had the highest Hepatitis B rates in the United States for over a decade.[832]

512. At present, the incidence of Hepatitis B in West Virginia is 14 times the national average,[833] while here again Cabell County has among the highest rates of Hepatitis B infections among West Virginia's counties, measuring 17 cases per 100,000 people in 2016.[834]

513. Dr. Feinberg testified that Endocarditis is most commonly caused by bacteria injected through the skin,[835] and that, although it is not actively surveilled, a recent study across four West Virginia hospitals that included two in Cabell and Huntington showed that a significant

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[828] 6/17/21 Trial Tr. (Feinberg) at 117.

[829] 6/17/21 Trial Tr. (Feinberg) at 128.

[830] 6/17/21 Trial Tr. (Feinberg) at 129.

[831] 6/17/21 Trial Tr. (Feinberg) at 130.

[832] 6/17/21 Trial Tr. (Feinberg) at 135-36.

[833] 6/17/21 Trial Tr. (Feinberg) at 136.

[834] 6/17/21 Trial Tr. (Feinberg) at 136.

[835] 6/17/21 Trial Tr. (Feinberg) at 140.

proportion of the 762 Endocarditis cases observed are in people in or near Cabell and Huntington.[836]

514. Dr. Feinberg thus concluded that "[t]here's no question in my mind" that the public health crises of bloodborne disease and of opioid use in Cabell County are related.[837]

515. Plaintiffs' epidemiology and OUD expert, Dr. Keyes, likewise concluded that exposure or supply of prescription opioids has a positive causal association with bloodborne diseases, including HIV, Hepatitis, and Endocarditis.[838]

e. Opioid Epidemic Harms—*Child and Family Disruption and Separation*

516. The Court finds that diversion of the prescription opioid pills Defendants shipped to Cabell and Huntington substantially contributed to the severe disruption of family and child welfare, including separation of children from their families, and the intergenerational transmission of OUD.

517. Plaintiffs' expert on the impact of opioids on children and families, Dr. Nancy Young, testified that the number of children placed into the child welfare system in the United States and West Virginia has been increasing since 2012 and that 80% of placements in West Virginia are related to substance abuse, the overwhelming number of which involve opioids.[839]

518. The opioid epidemic also has increased the percentage of children being placed with strangers rather than other family members, which is more likely to be trauma-inducing for

[836] 6/17/21 Trial Tr. (Feinberg) at 144.

[837] 6/17/21 Trial Tr. (Feinberg) at 159.

[838] 6/11/21 Trial Tr. (Keyes) at 183-84, 217-18.

[839] 6/16/21 Trial Tr. (Young) at 19-20, 33.

the children and to increase their own risk of developing OUD or suffering other adverse developmental effects.[840]

519. Dr. Young also testified that in Cabell and Huntington, data showed that at least 612 pregnant women have been admitted for treatment with OUD for prescription opioids,[841] where prenatal exposure increases the risk of distress, developmental delays, lower IQ, neuropsychiatric hospitalizations, lower educational attainment and need for special education services.[842]

520. Plaintiffs' epidemiology and OUD expert, Dr. Keyes, testified that the increased exposure to and supply of prescription opioids in the community has a positive causal association with child health harms, including development of Neonatal Abstinence Syndrome ("NAS").[843]

521. Plaintiffs' epidemiology and opioid abatement remedies expert, Dr. Alexander, testified that opioid addiction gets passed down "from grandparent to parent to child and so on," so that the opioid epidemic has created a need to "disrupt the cycle, the intergenerational perpetuation cycle of addiction[.]"[844]

522. Dr. Joseph Werthammer, a neonatologist at Cabell and Huntington Hospital's Neonatal Intensive Care Unit ("NICU"), testified that in 2012, approximately one-third of the NICU's patients were babies withdrawing from opioids,[845] and that Cabell and Huntington was

[840] 6/16 /21Trial Tr. (Young) at 22, 41.42, 46, 58-59.

[841] 6/16/21 Trial Tr. (Young) at 34.

[842] 6/16/21 Trial Tr. (Young) at 62.

[843] 6/14/21 Trial Tr. (Keyes) at 12.

[844] 6/28/21 Trial Tr. (Alexander) at 49-50.

[845] 5/21/21 Trial Tr. (Werthammer) at 14.

among the first hospitals to have a Neonatal Therapeutic Unit ("NTU") because of its high number of NAS patients.[846]

523. Dr. Werthammer further testified that West Virginia has the highest NAS rate of any state (5%), nearly doubling the next highest, and that the rate in Huntington at his hospital (10%) is double the rate of West Virginia as a whole.[847]

4. Defendants' Concurrent Contribution with Then-Prevailing Opioid Prescribing Standards to the Opioid Epidemic Harms in Cabell and Huntington

524. The Court finds that Defendants shipped tens of millions of opioid pills to Cabell County, the City of Huntington, and the surrounding region that were not prescribed in accordance with the standard of care, and instead were likely to be diverted to illicit, non-medical use, and that Defendants' systematic failures to maintain adequate and effective controls against diversion thus substantially contributed to these shipments and the resulting opioid epidemic harms in Cabell and Huntington.

a. Defendants' Shipments for Outlier Prescribers in Cabell and Huntington

525. Plaintiffs' data analytics expert, Ms. Lacey Keller, examined "outlier" opioid prescribing in Cabell and Huntington, which she defined as "something outside of the norm, something well above average, sometimes it's very visually – you're able to see it visually because the outlier is so extreme."[848]

[846] 5/21/21 Trial Tr. (Werthammer) at 15.

[847] 5/21/21 Trial Tr. (Werthammer) at 16-17.

[848] 6/15/21 Trial Tr. (Keller) at 60-61.

526. Ms. Keller further testified that Defendants "had access to or had in their possession [pharmacy] dispensing data that would allow them to identify outlier prescribers" in Cabell and Huntington.[849]

527. Among these outlier prescribers Ms. Keller identified was Dr. Deleno Webb of Huntington. Dr. Webb issued over 128,000 opioid prescriptions between 1997 and 2017, prescribing 14,431,799 opioid dosage units by himself.[850]

528. Dr. Webb was the largest opioid prescriber in Cabell County as measured both by opioid dosage units and morphine milligram equivalents ("MME's").[851]

529. Dr. Webb "was not only among the top 1 percent [of opioid prescribers] in Cabell County, but he was among the top .02 percent nationally."[852]

530. Dr. Webb's 14 million-plus prescribed opioid dosage units over this 20-year period would represent more than 10% of the total opioid dosage units that were shipped to Cabell County *as a whole* during the shorter ARCOS data period of 2006 to 2014 (127,902,911 opioid dosage units).[853]

531. In 2005, the West Virginia Workers' Compensation Commission banned Dr. Webb from receiving payment for treating injured workers based on claims that he was prescribing OxyContin without conducting physical examinations.[854]

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[849] 6/15/21 Trial Tr. (Keller) at 67.

[850] 6/15/21 Trial Tr. (Keller) at 117.

[851] 6/15/21 Trial Tr. (Keller) at 117.

[852] 6/15/21 Trial Tr. (Keller) at 66.

[853] 5/10/21 Trial Tr. (McCann) at 65.

[854] 6/15/21 Trial Tr. (Keller) at 123.

532. Dr. Webb nonetheless was able to continue to get prescriptions filled and, by 2011, was prescribing 1.1 million opioid dosage units annually, which Ms. Keller testified is "the equivalent of prescribing more than 130 pills for every hour of every day."[855]

533. Over 70% (or 10 million) of the prescription opioid dosage units written by Dr. Webb were filled at the Drug Emporium pharmacy store in Barboursville.[856]

534. Defendant ABDC was a primary distributor for Drug Emporium, supplying it with large quantities of oxycodone and hydrocodone.[857]

535. Other of Dr. Webb's opioid prescriptions were filled by a Medicine Shoppe pharmacy store.[858]

536. For the month of February 2012, Dr. Webb was far and away the Medicine Shoppe store's largest oxycodone prescriber, prescribing more than half (313 of 582) of the store's oxycodone prescriptions, and more than double the number of prescriptions of the store's next largest prescriber (119).[859]

537. Defendant Cardinal Health was the primary distributor for Medicine Shoppe, supplying it with large quantities of oxycodone and hydrocodone.[860]

[855] 6/15/21 Trial Tr. (Keller) at 130.

[856] 6/15/21 Trial Tr. (Keller) at 130.

[857] 5/10/21 Trial Tr. (McCann) at 121 124, 150.

[858] 6/15/21 Trial Tr. (Keller) at 76-77. 192-93.

[859] 6/15/21 Trial Tr. (Keller) at 77, 189.

[860] 5/10/21 Trial Tr. (McCann) at 133, 135, 138, 149.

538. Dr. Webb's prescribing ended in 2017, when he voluntarily surrendered his physician's license following a West Virginia Board of Medicine investigation into claims that he commonly treated patients with excessive dosages of opioids and benzodiazepines.[861]

539. Another outlier prescriber Ms. Keller identified was Dr. Philip Fisher, who prescribed 10 million opioid dosage units and 268 million MME's between 1997 and 2012.[862]

540. This made Dr. Fisher Cabell County's second largest opioid prescriber, just behind Dr. Webb, and placed him in the top .03 percent of opioid prescribers nationwide.[863]

541. Dr. Fisher's prescriptions were filled by, *inter alia*, SafeScript Pharmacy in Huntington, which was supplied by Defendant ABDC.[864]

542. Dr. Fisher's prescribing stopped in 2012 because his license was suspended when he was under investigation for using pre-signed prescription forms, improperly delegating authorization of prescription refills, failing to document treatment, and prescribing that was related to at least seven patient deaths.[865]

543. This evidence based just on Dr. Webb and Dr. Fisher and the 24 million-plus opioid dosage units they prescribed in Cabell County before losing their licenses undercuts Defendants' contention that the opioid epidemic was fueled solely or overwhelmingly by good faith prescribing within the prevailing standard of care.

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[861] 6/15/21 Trial Tr. (Keller) at 123.

[862] 6/15/21 Trial Tr. (Keller) at 117-18.

[863] 6/15/21 Trial Tr. (Keller) at 117-18; *id.* at 66.

[864] 5/19/21 Trial Tr. (Perry) at 131; P-16651 (7/29/2011 email from Perry to Hazewski re: Threshold Limits at Safescript Rx); 5/10 Trial Tr. (McCann) at 116, 119 describing ABDC's oxycodone shipments to SafeScript, which were far in excess of ABDC's national, state, and local average pharmacy order volumes).

[865] 6/15/21 Trial Tr. (Keller) at 117, 134-36.

544. The foregoing evidence is consistent with Mr. Rannazzisi's testimony that the DEA believes that:

> [E]ven just one physician who uses his/her DEA registration for criminal purposes can cause enormous harm. In the words of one commenter: 'It takes only a few untrained or unscrupulous physicians to create a large – large pockets of addicts.[866]

545. Ms. Keller's testimony shows that this is what happened in Cabell and Huntington, where available prescribing data showed that the "top 1 percent of prescribers, around 5 to 9 [prescribers], prescribed upwards of over 40 percent of dosage units and 60 percent of MME's in a given year."[867]

546. This prescribing by just five to nine doctors per year resulted in the shipment of over 80 million opioid dosage units and 1.6 billion MME's into Cabell and Huntington.[868]

547. Defendants' role in facilitating this voluminous opioid-prescribing outside of the prevailing standard of care makes their conduct a substantial contributing factor to the opioid epidemic in Cabell and Huntington.

b. Defendants' Shipments to Outlier Pharmacies in and around Cabell and Huntington

548. Plaintiffs' data processing expert, Dr. Craig McCann, performed a similar and more extensive analysis of Defendants' opioid shipments to pharmacies in Cabell County, the City of Huntington, and the surrounding region. The data he analyzes shows much the same—that Defendants' shipments do not solely or overwhelmingly reflect good faith prescribing pursuant to the standard of care, but rather that all three Defendants shipped quantities of oxycodone and

[866] 6/10/21 Trial Tr. (Rannazzisi) at 84-85.

[867] 6/15/21 Trial Tr. (Keller) at 61.

[868] 6/15/21 Trial Tr. (Keller) at 61.

hydrocodone to pharmacies in and near Cabell and Huntington that vastly exceeded their national, state, and local per-pharmacy shipment averages.

549. Defendant ABDC made per-pharmacy monthly oxycodone shipments averaging 5,036 dosage units nationally, 8,229 dosage units in West Virginia, and 10,743 dosage units in Cabell and Huntington.[869]

550. Yet ABDC's oxycodone shipments to the SafeScript pharmacy store in Huntington averaged 35,551 dosage units per month,[870] which is over seven times ABDC's national average, four times its West Virginia average, and three times its Cabell and Huntington average, and represents an excess of over 360,000 oxycodone dosage units per year that ABDC shipped into Cabell and Huntington. From January 2006 through February 2012, ABDC shipped SafeScript 3,888,340 doses of oxycodone and hydrocodone, or nearly 80 doses per person.[871]

551. Similarly, ABDC's oxycodone shipments to the McCloud Family Pharmacy in Huntington averaged 18,028 dosage units per month,[872] which is over 3.5 times ABDC's national average, double its West Virginia average, and almost double its Cabell and Huntington average, and represents an excess of over 150,000 oxycodone dosage units per year that ABDC shipped into Cabell and Huntington.

552. For three other West Virginia pharmacy stores outside Cabell County—Fritz's Pharmacy and Wellness; Bypass Pharmacy; and Four Season Pharmacy—ABDC's shipments of

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[869] 5/10/21 Trial Tr. (McCann) at 116.

[870] 5/10/21 Trial Tr. (McCann) at 116.

[871] P-44711_00044 (2006-2018 Opioid Shipments to Cabell County); P-43225_00001-6 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) & ECF No. 1433-7 at p. 28.

[872] 5/10/21 Trial Tr. (McCann) at 120.

oxycodone averaged 36,325, 41,735, and 31, 430 dosage units per month respectively,[873] which ranges from over six to over eight times ABDC's national average and three to four times it West Virginia average, and represents an excess of almost 95,000 oxycodone dosage units monthly and over 1,100,000 oxycodone dosage units per year that ABDC shipped into West Virginia, where the evidence demonstrates that diversion crosses state, county, and municipal boundaries.

553. ABDC also made per-pharmacy monthly hydrocodone shipments averaging 7,457 dosage units nationally, 14,448 dosage units in West Virginia, and 16,530 dosage units in Cabell and Huntington.[874]

554. Yet ABDC's hydrocodone shipments to Fruth Pharmacy #12 in Huntington averaged 46,285 dosage units per month,[875] which is over six times ABDC's national average, three times its West Virginia average, and well more than double its Cabell and Huntington average and represents an excess of over 460,000 hydrocodone dosage units per year that ABDC shipped into Cabell and Huntington.

555. Similarly, ABDC's hydrocodone shipments to Fruth Pharmacy #5 in Milton averaged 35,218 dosage units per month,[876] which is almost five times ABDC's national average, and more than double both its West Virginia and its Cabell and Huntington averages and represents an excess of over 330,000 hydrocodone dosage units per year that ABDC shipped into a Cabell County town of approximately 2,000 people.

556. For three other West Virginia pharmacy stores outside Cabell County—Fruth #1 in Mason County; Chapman Pharmacy; and Larry's Drive-In Pharmacy in Boon County—ABDC's

[873] 5/10/21 Trial Tr. (McCann) at 122.

[874] 5/10/21 Trial Tr. (McCann) at 124.

[875] 5/10/21 Trial Tr. (McCann) at 124.

[876] 5/10/21 Trial Tr. (McCann) at 124.

shipments of hydrocodone averaged 70,481, 58,268, and 67,457 dosage units per month respectively,[877] which ranges from almost eight to over nine times ABDC's national average and over four to almost five times its West Virginia average, and represents an excess of over 160,000 hydrocodone dosage units monthly and almost 2,000,000 hydrocodone dosage units per year that ABDC shipped into West Virginia, where the evidence demonstrates that diversion crosses state, county, and municipal boundaries.

557. Defendant Cardinal Health made per-pharmacy monthly oxycodone shipments averaging 4,975 dosage units nationally, 5,460 dosage units in West Virginia, and 6,989 dosage units in Cabell and Huntington.[878]

558. Yet Cardinal's oxycodone shipments to the Medicine Shoppe pharmacy store in Huntington averaged 18,644 dosage units per month,[879] which is over three times Cardinal's national and West Virginia averages and well over double its Cabell and Huntington average, and represents an excess of over 150,000 oxycodone dosage units per year that Cardinal shipped into Cabell and Huntington. Between January 2006 and December 2014, Cardinal sold and shipped 2,013,500 dosage units of oxycodone to the Medicine Shoppe in Cabell and Huntington – about 41 doses for every man, woman, and child in the city – from a single pharmacy.[880]

559. Similarly, Cardinal's oxycodone shipments to a CVS pharmacy store in Huntington averaged 14,292 dosage units per month,[881] which is almost three times Cardinal's national and

[877] 5/10/21 Trial Tr. (McCann) at 125-28.

[878] 5/10/21 Trial Tr. (McCann) at 132.

[879] 5/10/21 Trial Tr. (McCann) at 133.

[880] P-43225_00007 (2006-2014 ABDC, Cardinal, and McKesson Oxycodone and Hydrocodone Shipments to Cabell County) .

[881] 5/10/21 Trial Tr. (McCann) at 134.

West Virginia averages and more than double its Cabell and Huntington average and represents an excess of over 100,000 oxycodone dosage units per year that Cardinal shipped into Cabell and Huntington.

560. For Fruth #1 Pharmacy in Mason County, Cardinal's oxycodone shipments averaged 17,763 dosage units per month,[882] which is over three times Cardinal's national and West Virginia averages and more than double its Cabell and Huntington average and represents an excess of over 145,000 oxycodone dosage units per year that Cardinal shipped into the county neighboring Cabell and Huntington, where the evidence demonstrates that diversion crosses state, county, and municipal boundaries.

561. Cardinal also made per-pharmacy monthly hydrocodone shipments averaging 3,014 nationally, 7,005 dosage units in West Virginia, and 6,389 dosage units in Cabell and Huntington.[883]

562. Yet Cardinal's hydrocodone shipments to Fruth Pharmacy #12 in Huntington averaged 29,155 dosage units per month,[884] which is over nine times Cardinal's national average and over four times its West Virginia and Cardinal/Huntington averages and represents an excess of over 300,000 hydrocodone dosage units per year that Cardinal shipped into Cabell and Huntington.

563. For three other West Virginia pharmacy stores outside Cabell County—Family Discount; Fruth #1; and Hurley Drug—Cardinal's shipments of hydrocodone averaged 75,447, 55,391, and 39,092 dosage units per month respectively,[885] which ranges from 13 to 25 times

[882] 5/10/21 Trial Tr. (McCann) at 136.

[883] 5/10/21 Trial Tr. (McCann) at 137.

[884] 5/10/21 Trial Tr. (McCann) at 137.

[885] 5/10/21 Trial Tr. (McCann) at 138.

Cardinal's national average and five to eleven times its West Virginia and Cabell and Huntington averages, and represents an excess of over 160,000 hydrocodone dosage units monthly and almost 2,000,000 hydrocodone dosage units per year that Cardinal shipped into the region surrounding Cabell and Huntington, where the evidence demonstrates that diversion crosses state, county, and municipal boundaries.

564. Defendant McKesson Corporation made per-pharmacy monthly oxycodone shipments averaging 4,294 dosage units nationally, 4,559 dosage units in West Virginia, and 4,467 dosage units in Cabell and Huntington.[886]

565. Yet McKesson's oxycodone shipments to the Rite Aid #968 pharmacy store in Huntington averaged 7,552 dosage units per month,[887] which is over 1.5 times McKesson's national, West Virginia, and Cabell and Huntington averages, and represents an excess of almost 40,000 oxycodone dosage units per year that McKesson shipped into Cabell and Huntington.

566. For three other West Virginia pharmacy stores outside Cabell County—Crab Orchard Pharmacy; Colony Drug; and Meds 2 Go—McKesson's shipments of oxycodone averaged 25,002, 32,600, and 22,589 dosage units per month respectively,[888] which ranges from five to seven times McKesson's national, West Virginia, and Cabell and Huntington averages, and represents an excess of over 67,000 oxycodone dosage units monthly and over 800,000 oxycodone dosage units per year that McKesson shipped into West Virginia, where the evidence demonstrates that diversion crosses state, county, and municipal boundaries.

[886] 5/10/21 Trial Tr. (McCann) at 140.

[887] 5/10/21 Trial Tr. (McCann) at 141.

[888] 5/10/21 Trial Tr. (McCann) at 141-42.

567. Defendant McKesson Corporation made per-pharmacy monthly hydrocodone shipments averaging 4,086 dosage units nationally, 4,582 dosage units in West Virginia, and 2,102 dosage units in Cabell and Huntington.[889]

568. Yet McKesson's hydrocodone shipments to three West Virginia pharmacy stores outside Cabell County—Four Seasons; Larry's Drive-In; and Man Pharmacy—averaged 59,246, 43,068, and 40,517 dosage units per month respectively,[890] which ranges from 8 to 28 times McKesson's national, West Virginia, and Cabell and Huntington averages, and represents an excess of over 130,000 hydrocodone dosage units monthly and over 1,500,000 hydrocodone dosage units per year that McKesson shipped into West Virginia, where the evidence demonstrates that diversion crosses state, county, and municipal boundaries.

569. Two other southern West Virginia pharmacy stores to which McKesson distributed tell an even more shocking story.

570. From 2006 to 2014, McKesson shipped 5,818,020 hydrocodone and oxycodone pills, the vast majority of which was hydrocodone, to Family Discount Pharmacy in Mt. Shamrock, West Virginia, which had a population of just 1,700 people.[891]

571. McKesson's hydrocodone shipments to Family Discount Pharmacy averaged 197,341 dosage units per month,[892] which is almost 50 times McKesson's national average, and represents an excess of over 193,000 hydrocodone dosage units monthly and over 2,300,000 hydrocodone dosage units per year that McKesson shipped into this town of just 1,700 people in

[889] 5/10/21 Trial Tr. (McCann) at 143.

[890] 5/10/21 Trial Tr. (McCann) at 144.

[891] Hartle, 8/1/18 Dep. at 472.

[892] 5/10/21 Trial Tr. (McCann) at 144.

Southern West Virginia, where the evidence demonstrates that diversion crosses state, county, and municipal boundaries.

572. In 2006 and 2007, McKesson shipped 4,836,310 hydrocodone pills and 119,400 oxycodone pills to Sav-Rite Pharmacy in Kermit, West Virginia, which had a population of just 406 people.[893]

573. McKesson's hydrocodone shipments to Sav-Rite Pharmacy averaged at least 201,000 dosage units per month, which is almost 50 times McKesson's national average, and represents an excess of over 197,000 hydrocodone dosage units monthly and over 2,350,00 hydrocodone dosage units per year that McKesson shipped into this town of just 406 people in Southern West Virginia, where the evidence demonstrates that diversion crosses state, county, and municipal boundaries.

574. The DEA agreed with respect to these shipments that there is no conceivable medical need for a town of 400 people to receive almost 5,000,000 opioid pills in two years.[894]

575. The evidence thus strongly demonstrates that Defendants shipped tens of millions of highly addictive opioid pills to Cabell County, the City of Huntington, and the surrounding region that were not prescribed in accordance with the standard of care, but instead were likely to be diverted to illicit, non-medical use.

576. While Defendants have contended that most diversion of controlled substances takes the form of "medicine cabinet" diversion involving family or acquaintances for which Defendants bear no responsibility,[895] the Court rejects this contention.

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[893] Hartle, 8/1/18 Dep. at 450-55.

[894] Prevoznik, 4/18/19 30(b)(6) Dep. at 605-07.

[895] *See*, *e.g.*, ECF 1440-1 (Rule 52(c) Mtn. Memo of Law on Proximate Causation) at 24.

577. DEA investigations show that commercially based diversion involves far larger quantities of controlled substances than does the "medicine cabinet" diversion Defendants describe. As Mr. Rannazzisi read into the record, "DEA investigations clearly reveal that individuals illicitly ordering via the internet frequently receive 100 to 120 pills at a time. Thus, those who receive their drugs via rogue internet pharmacies are netting more pills than they would from friends or the family medicine cabinets."[896]

578. The Court further finds that where "medicine cabinet" diversion has occurred involving any of the millions of pills from flagged orders that Defendants shipped to Cabell and Huntington without performing adequate due diligence,[897] Defendants do bear responsibility for that diversion because it would not have occurred had they complied with their duties.

579. The Court therefore finds that Defendants' systematic failures to maintain adequate and effective controls against diversion substantially contributed to these shipments and to the resulting opioid epidemic harms in Cabell and Huntington.

B. The Opioid Epidemic Harms Were Reasonably Foreseeable to, and Foreseen by, Defendants.

580. The Court finds that the opioid epidemic public health and safety harms afflicting Cabell and Huntington were reasonably foreseeable to, and foreseen by, Defendants when they engaged in the diversion control failure conduct found and set forth herein.

581. The evidence before this Court abundantly demonstrates that the addiction-related public health harms of the opioid epidemic were reasonably foreseeable to, and foreseen by, Defendants.

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[896] 6/8/21 Trial Tr. (Rannazzisi) at 190-91.

[897] *See supra*, ¶¶ 369-70.

1. Foreseeability of Diversion

582. The DEA testified that it agrees with the statements that "diversion is foreseeable if registrants fail to comply with federal law[,]" and that "failure to comply with federal law enables more diversion."[898]

583. The DEA further testified that "DEA is of the opinion that increases in availability could have the unintended consequence of increasing diversion and abuse."[899]

584. Mr. Rannazzisi, testified that "[y]our Suspicious Order Monitoring Program is your tool" to prevent diversion.[900]

585. Plaintiffs' expert in the history of opiate use and abuse and drug policy, Dr. Courtwright, testified that the purpose of federal drug control laws "was to make sure that all narcotic transactions were confined to legitimate medical channels," and that there was "no way you could possibly accomplish that without supervising the whole chain from importation all the way down to pharmacist and the physician."[901]

586. Defendant McKesson Corporation testified that, "[u]sing common sense and basic logic, you could assume the more pills that are out there, the more potential for diversion there could be[,]" and agreed that "one of the foreseeable harms of engaging in unlawful conduct in the distribution of prescription opioids is diversion."[902]

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[898] Prevoznik, 4/18/19 30(b)(6) Dep. at 642.

[899] Strait, 5/31/19 30(b)(6) Dep. at 34-35.

[900] 6/7/21 Trial Tr. (Rannazzisi) at 180.

[901] 5/5/21 Trial Tr. (Courtwright) at 34.

[902] Hartle, 7/31/18 30(b)(6) Dep. at 268, 364.

587. McKesson's former Vice President of Regulatory Affairs and Compliance, Mr. Hartle, testified in his personal capacity that it is "fairly common sense" that "without sustained sources of supply, major diversion schemes wither away.").[903]

588. Defendant Cardinal Health's former Vice President of Quality and Regulatory Affairs, Steve Reardon, testified that he agrees that "when we're talking about suspicious orders, what we're trying to do is prevent diversion."[904]

589. Defendant ABDC's Director of Diversion Control and Security, Mr. Hazewski, testified that "based on information from the DEA and other industry sources, Oxycodone was a high risk for potential diversion[,]" and also that "[i]t was generally discussed information in the industry" that "people would travel to places like Florida and bring pills back into other areas like West Virginia[.]".[905]

590. Defendants' pain management and prescription opioids risks and benefits expert, Dr. Gilligan, testified that "if there are a large number of medications prescribed in any area, there will be some of them that will be diverted, misused, abused."[906]

2. Foreseeability of Opioid Epidemic Harms from Diversion and Oversupply

591. The DEA's former Deputy Assistant Administrator for the Office of Diversion Control, Mr. Rannazzisi testified that when the closed system of controlled substances distribution is breached and diversion occurs, the result is:

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[903] Hartle, 8/1/18 Dep. at 84-85.

[904] Reardon, 11/30/18 Dep. at 420-21.

[905] Hazewski, 10/25/19 Dep. at 61-62, 71-72; *see also* 5/27/21 Trial Tr. (Rafalski) at 151-152 (describing "people that would get on airplanes in Huntington and fly to Florida to go to the pain clinics to get pills and then come back"; "Allegiant flight that was – they called it the Pill Express").

[906] 7/2/21 Trial Tr. (Gilligan) at 159.

> The market being flooded, the illicit marketplace being flooded with opioids, benzodiazepines, mild stimulants, people becoming addicted, people overdosing, police officers required, being required to carry naloxone, which is not part of their duties up until a few years ago when we had to start carrying it because the overdoses were outrageous, and of course . . . losing loved ones.[907]

592. Plaintiffs' expert in the history of opiate use and abuse and drug policy, Dr. Courtwright, testified as to his agreement that "the historical record contain[s] evidence from primary sources that supply was a substantial factor in giving rise to the prior opioid epidemics in the United States[,]" and elaborated that "the per capita consumption of medicinal opiates in the United States tripled between 1870 and 1890, which was right in the heart of that first epidemic."[908]

593. Plaintiffs' neuroscience, addiction, and pain treatment expert, Dr. Waller, testified that, from a biological and neuroscientific perspective, the increase in exposure from increased supply of opioids makes increased addiction harms foreseeable:

> [W]hat happens as the dopamine goes down after they take it – and, again, especially in people who are opioid naïve or don't have other injuries or things like this, just taking an opioid does have those ramifications on the brain to varying degrees amongst individuals. But, at the same time, it is predictable in its nature . . . . And now, even though those were prescription and taken as prescribed, we now have someone that as we remove it, those behaviors of addiction become very apparent.[909]

594. Plaintiffs' epidemiology and OUD expert, Dr. Keyes, shows that increased supply and exposure made increased addiction and other public health harms foreseeable through her testimony on the strength of the scientific consensus over this connection: "I think there's consensus in my field that the strongest risk factor for Opioid Use Disorder is prescription opioid exposure.";[910] "My opinion is that there's substantial consensus in my field in epidemiological

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[907] 6/7/21 Trial Tr. (Rannazzisi) at 181.

[908] 5/5/21 Trial Tr. (Courtwright) at 28-29.

[909] 5/4/21 Trial Tr. (Waller) at 204-05.

[910] 6/11/21 Trial Tr. (Keyes) at 194.

literature to support a role for distribution of opioids and the creation of an opioid-rich environment in facilitation of the increase in prescription Opioid Use Disorder and the opioid crisis in the Cabell and Huntington community."[911]

595. Defendant McKesson Corporation provided testimony that "[t]he volume of opioids in the market and diversion is related to opioid deaths, certainly[,]" and agreeing that the:

> public health dangers associated with the diversion and abuse of controlled prescription drugs have been well-recognized over the years by Congress, DEA, HDMA and its members, and public health authorities.[912]

3. Foreseeability of Heroin and Fentanyl Abuse from Diversion and Oversupply of Prescription Opioids

596. Plaintiffs' neuroscience, addiction, and pain treatment expert, Dr. Waller, testified that prescription opioid and heroin abuse are closely related because of the drugs' identical molecular structures, whereby the human brain does not differentiate between them:

> I don't use a gateway. It's no different. I mean, for some people it doesn't – it's no different for them because when they take oxycodone or hydrocodone, for them if they have that same change in the brain chemistry, they might as well have taken [heroin]. It doesn't matter.[913]

597. Dr. Waller thus concluded that the "molecular structure and shape equals that you have the same structure, which gives you the same function, which gives you the same predictable outcome."[914]

598. Plaintiffs' epidemiology and OUD expert, Dr. Keyes, likewise demonstrates that this relationship is foreseeable through the strength of the consensus in her field and in medical literature generally on this point:

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[911] 6/15/21 Trial Tr. (Keyes) at 21.

[912] Hartle, 7/31/18 30(b)(6) Dep. at 294, 278.

[913] 5/4/21 Trial Tr. (Waller) at 71.

[914] 5/4/21 Trial Tr. (Waller) at 48.

- "'The tremendous expansion of long-acting prescription opioids led to . . . the transition of many to illicit opioids including fentanyl and its analogs which have subsequently driven exponential increases in overdose.'"[915]

- "I believe that the evidence in the medical literature is – overwhelmingly supports the validity of this statement."[916]

- "I believe my scientific writings would be consistent with the gateway effect. There's really no debate in the literature on that."[917]

599. Plaintiffs' epidemiology and opioid abatement expert, Dr. Alexander, testified that "prescription opioids and heroin and fentanyl are two sides of the same coin" because they "have the same effects on the body" and "produce the same type of physical dependency and the same risks of addiction."[918]

600. Defendant McKesson Corporation's former Vice President of Regulatory Affairs and Compliance, Mr. Hartle, testified that he has given presentations stating that "once people are addicted to opioids, narcotic opioids, their chances of them moving to heroin are dramatically increased."[919]

601. Defendants' pain management and prescription opioids risks and benefits expert, Dr. Gilligan, testified that "I think there's a direct relationship that includes the misuse and abuse of prescription opioids, along with many other predisposing factors, that then does relate to initiation of heroin."[920]

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[915] 6/11/21 Trial Tr. (Keyes) at 171 (quoting Association for Schools of Public Health consensus statement).

[916] 6/11/21 Trial Tr. (Keyes) at 172.

[917] 6/14/21 Trial Tr. (Keyes) at 218.

[918] 6/28/21 Trial Tr. (Alexander) at 26-27.

[919] Hartle, 8/1/18 Dep. at 480.

[920] 7/2/21 Trial Tr. (Gilligan) at 161-62.

602. Defendants' health economics expert, Dr. Murphy, testified in language strikingly similar to the testimony of Plaintiffs' expert, Dr. Waller, that "I would say if you focus on abuse of prescription opioids and abuse of heroin, they're probably closer to be[ing] substitutes. . . . And substitute would be like Coke or Pepsi."[921]

603. The Court finds that Defendants could reasonably foresee, and in fact foresaw, that their diversion control failures as found herein would result in the opioid epidemic public health and safety harms afflicting Cabell and Huntington, including the epidemic's evolution from one primarily of prescription opioid abuse to one intertwined with heroin and fentanyl abuse.

IV. Plaintiffs' Abatement Plan Will Abate the Public Nuisance of the Opioid Epidemic in Cabell and Huntington.

604. The Court finds to a reasonable degree of certainty that Plaintiffs' proposed Abatement Plan is necessary to abate the opioid epidemic harms in Cabell and Huntington caused by Defendants' conduct, and that the Abatement Plan's 15-year cost, measured in future value, is $2,544,446,548.

A. The Abatement Plan Redresses the Opioid Epidemic Harms Caused by Defendants' Conduct.

605. Plaintiffs offered expert testimony regarding abatement from Dr. G. Caleb Alexander, a Professor of Epidemiology and Medicine and practicing internist at Johns Hopkins. Dr. Alexander has authored or co-authored more than 325 scientific articles, editorials, and book chapters, including roughly 50 peer-reviewed publications about the opioid epidemic. He co-edited a Johns Hopkins report entitled "The Opioid Epidemic: From Evidence to Impact," on comprehensive evidence-based solutions to the opioid epidemic.[922] He has testified about the

[921] 7/8/21 Trial Tr. (Murphy) at 147.

[922] 6/28/21 Trial Tr. (Alexander) at 9-11.

opioid epidemic before the U.S. Senate, U.S. House of Representatives, Food and Drug Administration, and other bodies.[923] Defendants did not challenge his qualifications and the Court accepted him as an expert in the field of epidemiology and opioid abatement interventions.[924]

606. Dr. Alexander testified that there is an opioid epidemic in Cabell and Huntington, identified what evidence-based programs would abate the epidemic, estimated the population needs for each abatement program, and identified the cost of certain of the abatement programs.[925] Dr. Alexander created a comprehensive "Abatement Plan," consisting of dozens of programs which he concludes will abate the opioid epidemic in Cabell and Huntington, including reducing the incidence of OUD, overdoses, infectious diseases, and related harms to opioid users and the broader Community.[926]

607. Dr. Alexander's analysis of Cabell and Huntington's opioid epidemic and local abatement needs was extensively researched and reflects a consensus among national and local experts regarding what interventions are needed to reduce mortality and other harms related to opioids. He spoke with dozens of leaders in Cabell and Huntington, including the police and fire chiefs, academics, medical doctors, treatment providers, program administrators, and Mayor Williams, to understand the epidemic and the community's abatement needs. He researched local, state, and national reports on abatement; peer-reviewed academic studies about the efficacy of abatement programs; and data from the West Virginia Department of Health and Human Services, the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services

[923] 6/28/21 Trial Tr. (Alexander) at 16.

[924] 6/28/21 Trial Tr. (Alexander) at 18-19.

[925] 6/28/21 Trial Tr. (Alexander) at 19, 30.

[926] 6/28/21 Trial Tr. (Alexander) at 29.

Administration, and other sources about the epidemic and abatement. These are the same kinds of sources that epidemiologists use in other work.[927]

608. In creating the Abatement Plan, Dr. Alexander also studied existing programs in Cabell and Huntington for addressing OUD, overdoses, NAS, and other harms that have been implemented in response to the epidemic. He cited programs including PROACT, the addiction treatment program; Lily's Place and a neonatal therapeutic unit for babies with NAS; MARC and MOMS for pregnant women with addiction; the Quick Response Team ("QRT"), which provides multidisciplinary outreach within 72 hours of overdose; the Drug Court and WEAR criminal-justice program; and harm reduction initiatives, including syringe exchange, naloxone, and fentanyl testing.[928]

609. Dr. Alexander's testimony demonstrates that the opioid epidemic in Cabell and Huntington is a single, indivisible condition in which the different harms are integrally interrelated:

> It's an opioid epidemic. I mean, prescription opioids and heroin and fentanyl are two sides of the same coin. They have the same effects on the body. They produce the same type of physical dependency and the same risks of addiction.
>
> So while the community in the early stages of the epidemic was predominantly flooded with prescription opioids and while now heroin and illicit fentanyl have taken on heightened concern, I would characterize the epidemic as an opioid epidemic, not on of one particular type of opioid or another.[929]

610. Dr. Alexander thus concluded that "there's one epidemic, not two; an opioid epidemic, not a prescription epidemic and a fentanyl and heroin epidemic."[930]

611. Based on Dr. Alexander's reliable testimony, the Court finds that:

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[927] 6/28/21 Trial Tr. (Alexander) at 21-23, 30-31.

[928] 6/28/21 Trial Tr. (Alexander) at 33-34.

[929] 6/28/21 Trial Tr. (Alexander) at 26-27.

[930] 6/28/21 Trial Tr. (Alexander) at 120-21.

a. There is "abundant evidence" of an ongoing opioid epidemic in Cabell and Huntington. The Community has had a "flood" of prescription opioids, "enough to provide each adult and child 400 tablets a year." Fatal overdose rates, at their peak, were "off the charts," and there were 137 overdose deaths in 2018. 7,900 people are estimated to have OUD, which constitutes 8 or 9 percent of the population. Rates of emergency room visits are very high, rates of NAS are far above average, and the school system and child welfare system shoulder significant burdens.[931]

b. Ongoing morbidity and mortality related to opioids show that the opioid epidemic is ongoing.[932]

c. There is an intergenerational cycle of addiction in Cabell and Huntington. Having a parent or other household member with substance use disorder is a significant risk factor for a child to develop substance use disorder.[933]

d. There is a single opioid epidemic, encompassing both prescription and illicit opioids, although in the early stages of the epidemic Cabell and Huntington was predominantly flooded with prescription opioids.[934]

e. The opioid epidemic is an "existential threat" to Cabell and Huntington. It is necessary to abate the epidemic and for the long-term health and stability of Cabell and Huntington.[935]

612. Testimony of other expert and fact witnesses confirms that the harms arising from the opioid epidemic are ongoing and will continue if not abated.[936] Dr. Smith testified that

[931] 6/28/21 Trial Tr. (Alexander) at 24-26.

[932] 6/28/21 Trial Tr. (Alexander) at 28.

[933] 6/28/21 Trial Tr. (Alexander) at 49.

[934] 6/28/21 Trial Tr. (Alexander) at 26-27.

[935] 6/28/21 Trial Tr. (Alexander) at 111.

[936] 6/17/21 Trial Tr. (Feinberg) at 109 (infections associated with IV and other drug use are serious part of the public health crisis of opioid epidemic); 5/27/21 Trial Tr. (Zerkle) at 184-85 (Crimes connected to opioid epidemic include shoplifting, burglary, theft, disorderly conduct, DUI); 6/14/21 Trial Tr. (Keyes) at 12 (harms to children and families occur when opioid use is high); 6/30/21 Trial Tr. (Williams) at 46 (as epidemic unfolded, City's neighborhoods were crumbling); 5/27/21 Trial Tr. (Zerkle) at 119-20 (addiction draining workforce in County, declining population and tax base; City of Huntington owns 350+ abandoned homes); 6/28/21 Trial Tr. (Alexander) at 25 (opioid epidemic in Cabell and Huntington includes burdened child welfare system and strained school system).

prescription opioids continue to play an important role in drug overdose deaths in West Virginia.[937] Dr. Yingling testified that the opioid epidemic is a "generational problem."[938] Even Defendants' experts concede this. Dr. Gilligan stated that closing the path to opioid use disorder will require addressing over-prescription of legal opioids, reducing the availability of illicit opioids and getting patients with opiate use disorder into treatment.[939]

613. Cabell and Huntington are limited by existing human and economic resources and need additional resources to help abate the opioid epidemic.[940]

614. After testifying to the existence of an opioid epidemic in Cabell and Huntington as described above, Dr. Alexander testified about programs to abate the epidemic locally. Based on his reliable testimony, the Court finds that:

a. There is strong consensus among experts about what needs to be done to address the opioid epidemic, and the efficacy of specific abatement programs. These programs have a robust scientific evidence base.[941]

b. Plaintiffs' Abatement Plan, recommended by Dr. Alexander, is "highly consistent" with abatement recommendations contained in governmental reports about the opioid epidemic, including a Trump Administration report, a Johns Hopkins report that Dr. Alexander co-authored,

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[937] 6/10/21 Trial Tr. (Smith) at 153.

[938] 6/16/21 Trial Tr. (Yingling) at 162-64.

[939] 7/2/21 Trial Tr. (Gilligan) at 179-180.

[940] *See* 5/28/21 Trial Tr. (O'Connell) at 22-23 (the community sees the value of preventive measures, and they need more support to expand), 25-26 (community needs greater information and resources on effective NAS interventions), 28-29 (community needs greater support for round-the-clock outpatient treatment), 30 (community needs resources to expand prevention and early intervention beyond Huntington into rural parts of Cabell County), 31-32 (community needs resources to expand wellness services for law enforcement and treatment providers); 5/21/21 Trial Tr. (Werthammer) at 21 (with proper resources and healthcare infrastructure, Cabell and Huntington could make a dramatic impact on the opioid epidemic); 6/29/21 (Barrett) at 168 (what Huntington has done to date is limited by available resources); *see also* 5/26/21 Trial Tr. (Yingling) at 167 (Resiliency Plan represents the best the community can do with its existing human and economic resources).

[941] 6/28/21 Trial Tr. (Alexander) at 32, 71, 123.

Huntington's City of Solutions report, Cabell County's Resiliency Plan, and the Huntington Mayor's Office of Drug Control Policy's Strategic Plans.[942]

c. The Abatement Plan consists of programs which are likely to have the greatest impact on mitigating the epidemic.[943]

d. Existing local programs in Cabell and Huntington are insufficient to address the epidemic. Such programs are not as comprehensive as the Abatement Plan, many programs are at or near capacity, funding for current programs is unstable, and rates of fatal overdose and addiction continue to be very high.[944]

e. There is a need to increase both the availability of addiction treatment programs and take-up rates, and programs must be scaled up if the epidemic is to be abated.[945]

f. The Abatement Plan is necessary to provide the level of services and security needed to address the opioid epidemic.[946]

g. Implementing the Abatement Plan will prevent harms in the future which would occur but for the Plan's interventions.[947]

g. The harms resulting from the opioid epidemic are capable of being abated.[948]

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[942] 6/28/21 Trial Tr. (Alexander) at 31-32.

[943] 6/28/21 Trial Tr. (Alexander) at 31-32.

[944] 6/28/21 Trial Tr. (Alexander) at 34-36. Dr. Alexander testified that Cabell and Huntington is experiencing wait lists where treatment programs are at or near capacity and barriers because individuals that are struggling to maintain treatment also have other factors that contribute to or make it more difficult for them to participate in treatment. *Id.* at 54.

[945] 6/28/21 Trial Tr. (Alexander) at 54.

[946] 6/28/21 Trial Tr. (Alexander) at 110-11.

[947] 6/28/21 Trial Tr. (Alexander) at 110-11.

[948] 6/28/21 Trial Tr. (Alexander) at 32 (there is "clear evidence" that opioid epidemic in Cabell and Huntington can be abated).

i. The Abatement Plan will be effective and reduce harms.[949] Based on his experience and research, Dr. Alexander estimates that rates of death and OUD would decrease by 50% in 15 years if the Abatement Plan is implemented, which would be a very meaningful reduction.[950]

j. Implementing the Abatement Plan is feasible and Cabell and Huntington has the capacity to carry out the Abatement Plan, including an existing treatment infrastructure to build on.[951]

615. Testimony from additional experts and fact witnesses corroborates Dr. Alexander's testimony. A number of programs aimed at addressing the opioid epidemic locally have been successful. Cabell County's syringe program is a "model" program and one year of data shows 2,000 individuals served with almost 8,000 encounters.[952] Mayor Williams has observed many people who have become successful in overcoming their addiction through treatment and resources offered by the community.[953] Connie Priddy testified that the Quick Response Team reaches between 50-60% of individuals of suspected overdose patients, of which 30% go into treatment.[954] Jan Rader explained that Drug Court is a treatment court, where individuals can rebuild their lives and gain confidence.[955]

616. Witnesses testified that there are evidence-based solutions that have been proven to help abate the opioid epidemic, which can be put in place in Cabell and Huntington.[956] Harm

[949] 6/28/21 Trial Tr. (Alexander) at 71.

[950] 6/28/21 Trial Tr. (Alexander) at 29, 36, 80, 97-99.

[951] 6/28/21 Trial Tr. (Alexander) at 92, 110-11, 113-14 (Huntington and Cabell County can fight the opioid epidemic if given the resources, coordination, and opportunity), 133, 141.

[952] 6/17/21 Trial Tr. (Feinberg) at 155-56.

[953] 6/30/21 Trial Tr. (Williams) at 74.

[954] 5/7/21 Trial Tr. (Priddy) at 15-16.

[955] 5/7/21 Trial Tr. (Rader) at 49-50.

[956] *See* 5/4/21 Trial Tr. (Waller) at 207-212 (efficacy of provider education and training, opioid use prevention, expansion of medication treatment of OUD); 5/27/21 Trial Tr. (Zerkle) at 106-07

reduction programs have been found to facilitate further treatment services, since people using such programs are five times as likely to enter drug treatment and three times as likely to reduce their frequency of injection.[957]

617. Plaintiffs presented evidence that Hepatitis C and infectious diseases are caused by opioid use. Studies show a positive return on investment from community education and infectious disease screening.[958] Plaintiffs also presented evidence of the effectiveness of early support for infants with prenatal opioid exposure, intervention services for pre-school children in opioid-effected families, specialized services to address children of adults with OUD, and support services

(describing County's expansion from one to five full-time school resource officers (SRO's), police officers placed in schools for supervision and mentorship); *id.* at 188 (more recovery centers and beds, and mental health counseling would help with fixing the epidemic); 5/27/21 Trial Tr. (O'Connell) at 213-14 (describing the success of local early-intervention programs and QRT), 216 (PROACT is currently seeing 500+ patients), 217 (Healthy Connections, coordinated services for pregnant, parenting families), 218 (describing coordinated therapy, developmental psychology, social work, communication disorders treatment), 224 (Project Hope provides support for families in community), 230-31 (Community coordination can ensure training of professionals to provide MAT), 232 (CORE prepares people in recovery for the workforce); 6/7/21 Trial Tr. (O'Connell) at 147-48 (PROACT provides treatment services not otherwise immediately available), 148-49 (MARC dramatically increased treatment of infants with exposure), 149 (MOMS is necessary to provide maternal treatment), 149-50 (Lily's Place is necessary to provide a community-based setting for exposed infants), 150 (other listed programs likewise met a specific need for populations not being served); 6/16/21 Trial Tr. (Yingling) at 161 (Project Hope provides a facility for mothers to stay with their newborns during long-term NAS recovery); 6/17/21 Trial Tr. (Holbrook) at 220 (HPD combatted diversion through education, prevention, and enforcement), 221 (Neighborhood Institute allowed Huntington police to obtain, share information, better address epidemic challenges in city neighborhoods), 223-24 (HPD prevention efforts included public service announcements, school visits, a drug take-back program, and community education).

[957] 6/17/21 Trial Tr. (Feinberg) at 152-153, 157-58.

[958] 6/17/21 Trial Tr. (Feinberg) at 159 ("no question" that "there's a public health crisis in Cabell County as it relates to bloodborne diseases resulting from opioid use"), 176 (opioid use in Appalachian region exacerbated the use of street drugs); 6/16/21 Trial Tr. (Yingling) at 156-57 (Cabell County opioid epidemic morbidities include infections, Hep B, Hep C, HIV, maternal addiction, NAS, endocarditis, abscesses, spinal cord abscesses, hospital overflow, long-term care needs).

for adolescents developing or at risk of substance abuse.[959] Plaintiffs also presented testimony about the need and importance of shortening the waiting period before entry into parent and child support services, family treatment programs, medication-assisted treatment (MAT)—including for pregnant women—and education and support for infants and children exposed to opioids.[960]

618. Witnesses also established that sufficient abatement resources to fund prevention, treatment, and recovery programs would have a dramatic impact on the opioid epidemic, but more is needed.[961] Connie Priddy testified that more resources and help are needed to get individuals suffering from addiction into treatment; such resources include a QRT follow-up team, health and wellness events for community outreach, and transportation.[962] The PROACT treatment facility

[959] *See* 6/16/21 Trial Tr. (Young) at 39 (preschool children in opioid-affected families benefit from intervention services), 46-47 (infants with prenatal opioid exposure benefit from developmental assessments), 47-48 (children of adults with OUD need specialized services to address unique emotional challenges), 49 (support services for adolescents developing substance abuse are beneficial), 54 (literature shows effectiveness of supports for infants aged 1-2 years at preventing later developmental needs), 59-60 (opioid-exposed infants need interventions beyond the hospitalization period, i.e. early intervention and special education services), 62 (adverse developmental and educational outcomes for opioid-exposed infants worsen over time without intervention; studies show positive impact of interventions).

[960] *See* 6/16/21 Trial Tr. (Young) at 35 (evidence shows that shortening the time before entry into parent and child support services improves family reunification outcomes), 50-53 (pregnant women with opioid addiction need access to MAT, education and support for infants with NAS), 51-52 (West Virginia data shows a big gap between pregnant women needing and receiving support services), 53-54 (evidence shows effectiveness of family treatment program in residential care for mothers and infants).

[961] *See* 5/5/21 Trial Tr. (Gupta) at 115-16 (only 31% of overdose deaths showed past Naloxone use; report recommends expanded access), 127-28 (only 7% of overdose decedents had received MAT), 131 (report recommends patient medical interventions, prevention, and greater prescription monitoring), 142 (report recommends further surveillance, healthcare system response, and community response); 5/21/21 Trial Tr. (Werthammer) at 21 (with proper resources, healthcare infrastructure in Cabell and Huntington could make a dramatic impact on the opioid epidemic).

[962] 5/7/21 Trial Tr. (Priddy) at 15.

is at capacity and needs to be expanded.[963] Access to treatment via transportation is a community need and a barrier to care, as is limited hours (9 to 5) for outpatient treatment.[964]

619. Evidence established that funding sources for existing opioid-related programs in Cabell and Huntington are limited and unreliable.[965] It is not reasonably certain that funding will be available to fully fund the Abatement Plan or even continue the existing programs. Programs and services required to abate the pervasive and long-term harm in Cabell and Huntington require consistent and reliable funding over time.[966] Addiction treatment cannot be delivered in fits and starts; it requires constancy to be effective. As is, the City and County spend a disproportionate amount of time seeking grant funding.[967] To support Cabell and Huntington's recovery, the Abatement Plan's "scaffolding" must be built over time, remain securely in place while the work is done, and then be taken down gradually.[968]

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[963] 5/7/21 Trial Tr. (Rader) at 57-58.

[964] 5/28/21 Trial Tr. 20 (O'Connell) at 28-29.

[965] *See* 6/7/21 Trial Tr. (O'Connell) at 144-47 (no Medicaid or insurance funding for the Compass program, harm reduction services, QRT, CORE); 6/16/21 Trial Tr. (Young) at 36 (existing grant funding is insufficient to sustain needed family support services), 39 (grant funding does not sustain needed child pre-school intervention services), 47 (federally-funded services for young children with prenatal opioid exposure often are waitlisted), 60 (early intervention and special education services for opioid-exposed infants are not fully funded by federal funds).

[966] *See* 5/28/21 Trial Tr. (O'Connell) at 32-36 (current programs are grant funded, subject to termination), 36 (community needs long-term, sustainable, reliable funding to make its epidemic response efforts work); 5/27/21 Trial Tr. (Zerkle) at 111-12 (County has relied on grant funding to re-equip SWAT Team); at 118 (County applying for USDOH grant to fund police officer overtime pay); 5/6/21 Trial Tr. (Priddy) at 203 (County EMS applying for federal grants for Quick Response Team (QRT) funding); at 206 (QRT lacks funding for weekend shifts); at 213 (QRT needs reliable, sustainable funding);

[967] *See* 5/6/21 Trial Tr. (Priddy) at 203; 5/27/21 Trial Tr. (Zerkle) at 111-12, 118; 5/28/21 Trial Tr. (O'Connell) at 32-36.

[968] 6/28/21 Trial Tr. (Alexander) at 99.

620. Moreover, as explained in the Court's Conclusions of Law, because Defendants created a public nuisance in Cabell and Huntington, they are liable for the full cost of abating the nuisance.[969] Any funding of abatement programs in Cabell and Huntington by the City and County, the West Virginia and federal government, and other grants effectively shifts the financial burden of Defendants' public nuisance to Plaintiffs and third parties, including taxpayers.

621. Defendants have alleged that the Abatement Plan would be a "windfall" for Plaintiffs; that the existence of some programs addressing the opioid epidemic means Cabell and Huntington has capacity to abate the epidemic on its own, using current resources; that nothing more is needed.[970] On the contrary, the Court agrees with Plaintiffs that to the extent Plaintiffs and third parties—the West Virginia state government, Medicare and Medicaid, private insurers, and others—are paying to address the effects of the opioid epidemic in Cabell and Huntington,[971] those payments are a windfall *to Defendants*. Plaintiffs and third parties are subsidizing the cost of addressing harms caused by Defendants' wrongdoing. Plaintiffs and third parties are reducing the scale of the epidemic that Defendants must abate.

622. Importantly, the City and County did not choose to be the target of this public nuisance, in the form of the local opioid epidemic. Abatement efforts at the local level must be viewed in that context, as efforts made under duress, with limited resources, to address an urgent and overwhelming epidemic.[972]

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[969] Conclusions of Law ("COL"), *infra,* Part VII(B)(4).

[970] ECF 1441-1 (Memo of Law ISO Rule 52(c) Motion on Abatement) at 19-20.

[971] *See*, *e.g.*, 5/6/21 Trial Tr. (Priddy) at 203; 5/27/21 Trial Tr. (Zerkle) at 111-12, 118; 5/28/21 Trial Tr. (O'Connell) at 32-36.

[972] *See*, *e.g.*, P-41527_00001 (2014 HPD Threat Assessment) (describing diversion and abuse of prescription drugs along with the pervasive drug culture and associated crime as the greatest threats to ever face the community)

623. Plaintiffs also confirmed through testimony that the City and County have the institutional capacity to carry out the Abatement Plan. Some programs aimed at abating the opioid epidemic already exist there, whether offered through the City and County (like the CHHD harm-reduction program) or third parties (like private treatment centers).[973] Large institutions like Marshall University and Marshall Health have capacity to implement programs.[974] The community has the laid a solid foundation for addressing the epidemic through collaboration with community partners.[975] Mayor Williams testified that the community has collaborated with the Cabell and Huntington Health Department, Marshall University (on research and leadership), hospitals, the faith community, and emergency medical services (on real-time data).[976] The Mayor's Office of Drug Control Policy brought other groups together and created an opportunity for collaboration, creating a talented community network.[977]

624. The Court agrees with and hereby adopts Judge Polster's recognition that "there is no realistic way the Court could order . . . that . . . Defendants abate the [opioid] crisis themselves" because "Defendants do not have the requisite infrastructure . . . ."[978] Whereas the City and County have institutional capacity to implement the Abatement Plan, Defendants do not. Defendants do not currently offer any of the programs recommended in the Abatement Plan. They do not pay for any programs aimed at abating the opioid epidemic in Cabell and Huntington. As drug distribution

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[973] *See* 6/28/21 Trial Tr. (Alexander) at 92, 110-11, 113-14 (Huntington and Cabell County can fight the opioid epidemic if given the resources, coordination, and opportunity), 133, 141.

[974] 6/28/21 Trial Tr. (Alexander) at 113-14.

[975] 5/28/21 Trial Tr. (O'Connell) at 27.

[976] 6/30/21 Trial Tr. (Williams) at 64-65.

[977] 6/30/21 Trial Tr. (Williams) at 69-71.

[978] *In re Nat'l Prescr. Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4043938, at *2 (N.D. Ohio Aug. 26, 2019).

companies—as compared to governmental entities, healthcare providers, social-services providers, or academic institutions—Defendants are ill-equipped to offer any of the Abatement Plan's programs.

625. Dr. Alexander recommends a 15-year duration for the Abatement Plan, from 2021 to 2035, since an effective plan will take time to ramp up and be successful.[979] The Court finds it reasonably certain that abatement of the opioid epidemic cannot be accomplished in a single year, and the 15-year Abatement Plan proposed by the Plaintiffs is reasonably necessary.[980] The opioid epidemic is ongoing. Individuals with OUD will require ongoing services to address their addiction and to reintegrate them successfully, and other individuals using prescription opioids or exposed to illicit opioids in the community will develop addiction. The same is true, as Dr. Young and Dr. Alexander testified, of children at a higher risk of developing substance abuse disorders due to parental opioid use. As a result, addressing the epidemic will require addressing people who will develop OUD in the future.[981]

626. Plaintiffs' Abatement Plan consists of four broad categories of abatement needs: Category 1, Prevention - Reducing Opioid Oversupply and Improving Safe Opioid Use; Category 2, Treatment - Supporting Individuals Affected by the Epidemic; Category 3, Recovery - Enhancing Public Safety and Reintegration; and Category 4, Addressing Needs of Special Populations. Each category contains multiple subcategories and one or more individual programs

[979] 6/28/21 Trial Tr. (Alexander) at 99.

[980] 6/28/21 Trial Tr. (Alexander) at 99 (15-year duration represents balancing of time to ramp up, reachable from present).

[981] 6/28/21 Trial Tr. (Alexander) at 31.

within each subcategory. The Abatement Plan comprehensively but programmatically addresses the Community's opioid epidemic, including overdoses, OUD, and other health problems.[982]

627. For each program, the Abatement Plan includes an estimate of relevant populations in need of given services, the frequency needed for each service, and medical-related costs for services based on reliable sources.[983] The population measures in the Abatement Plan are dynamic, with most populations changing year over year as interventions take hold. For example, the population of people in treatment increases over time while the total OUD population decreases over time. Dr. Alexander draws on his own expertise and four academic studies, including with Markov models that forecast population changes.[984]

628. Category 1 of the Abatement plan, Prevention, contains six subcategories: Health Professional Education, Patient and Public Education, Safe Storage and Drug Disposal Programs, Community Prevention and Resiliency, Harm Reduction, and Surveillance, Evaluation, and Leadership.[985] The programs include health professional education about opioid supply and treatment, focusing on the highest-volume prescribers; patient and public education regarding the limited efficacy and serious risks of prescription opioids; safe storage and drug disposal to reduce the risks created by excess supply and avoid diversion; community prevention and resiliency (including a community center); harm reduction to minimize the risk of overdose; and surveillance, education, and leadership to refine the plan over time.[986] These programs focus on preventing

[982] 6/28/21 Trial Tr. (Alexander) at 129-45.

[983] 6/28/21 Trial Tr. (Alexander) at 72-76.

[984] 6/28/21 Trial Tr. (Alexander) at 21-22, 92, 101, 150, 177-80, 190-98.

[985] 6/29/21 Trial Tr. (Barrett) at 102-03, 106-11.

[986] *See* 6/28/21 Trial Tr. (Alexander) at 36-38.

further cases of OUD and ensuring that people with OUD do not die. There is a "mountain of evidence" that these programs are effective.[987]

629. The Court notes that subcategory 1F of Dr. Alexander's Abatement Plan recommends funding for "Surveillance, Evaluation, and Leadership," including the collection of data.[988] Dr. Alexander explained:

> [S]urveillance, evaluation, and leadership is important because there has to be a mission control to this plan. Surveillance and evaluation allow for iterative refinement and fine-tuning of the plan over time as the epidemic continues to evolve. And leadership is important because the governance of this overall plan will be vital. And I think the community has what it takes. . . .
>
> And the bottom line is that Cabell County and the City of Huntington are fortunate to have some data points that can be used to understand how varied interventions are performing and to refine . . . the investment of resources. So, the plan is -- is a plan that allows for flexibility because it's unclear what's around the corner. The epidemic has continued to change and evolve over time. And so, it's important not only that there's a governance, and my -- my plan includes opportunities for governance, but also that there's ongoing surveillance.[989]

630. Category 2 of the Abatement Plan, Treatment, contains five subcategories: Connecting Individuals to Care, Treating Opioid Use Disorder, Managing Complications Attributable to the Epidemic, Expanding the Healthcare Workforce, and Distributing Naloxone and Providing Training.[990] The Plan creates the necessary treatment infrastructure, expands the treatment workforce, and connects individuals to care (including programs to decrease relapse and increase retention in treatment).[991] This category includes treatment for OUD and resulting harms

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[987] 6/28/21 Trial Tr. (Alexander) at 45-46.

[988] 6/28 Trial Tr. (Alexander) at 136-37.

[989] 6/28 Trial Tr. (Alexander) 37:4-38:19, 102:18-103:10.

[990] 6/28/21 Trial Tr. (Alexander) at 47-52.

[991] Trial Tr. June 28, 2021 (Alexander) at 47-52 (The plan recommends four types of treatment: inpatient, residential health, intensive outpatient, and routine inpatient. The Plan encompasses treatment for opioid use disorder, connecting individuals to care, including Quick Response

such as infectious diseases. OUD treatment services consist of four categories: inpatient, residential rehabilitation, intensive outpatient, and routine outpatient. Some patients require more intensive treatment than others. Dr. Alexander's estimate of the number of people needing treatment is based on Dr. Keyes's estimate of Cabell and Huntington's opioid-addicted population.[992]

631. The Defendants argue that Dr. Alexander's abatement plan overstates treatment need for UUD treatment because another Plaintiff's expert, Dr. Waller, testified that "the one-year success rate for OUD treatment is approximately 84%."[993] From this misrepresentation of Dr. Waller's testimony, Defendants jump to the conclusion that a large majority of the treatment expenses included in the abatement plan are not recoverable for individuals who do not currently have OUD. Defendants are factually wrong.

632. Dr. Waller was asked about "the short-term remission rate after one year" and testified that among "people on the medication" (i.e., patients who remain in medication-assisted treatment), the rate reflected in the academic literature is 70%.[994] Thus, Dr. Waller's testimony referred to the "remission rate" among a subpopulation of individuals who receive medication-assisted treatment and remain in treatment for a full year; it did not refer to all individuals who

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Teams, managing the complications of addiction, workforce expansion and resiliency, and naloxone distribution and training to reverse overdoses).

[992] 6/28/21 Trial Tr. (Alexander) at 89-90.

[993] Doc. 1451 at 16 (citing 5/4 Tr. (Waller) at 216:6–15).

[994] 5/4 Tr. (Waller) at 216. The 84% figure defendants rely on for their argument refers to the corresponding rate that Dr. Waller has achieved in his practice. However, there is no basis for applying that rate to the population of individuals to receive treatment under Dr. Alexander's abatement plan. For example, there is no indication of the distribution of levels of care (outpatient, outpatient intensive, rehabilitation and residential, or inpatient), the number of patients surveyed, or whether the patients are representative of the patient population in Cabell County or constitute a random sample. *See* 6/28 Tr. (Alexander) at 93-94. (Dr. Alexander testifying about American Society of Addiction Medicine levels of care).

enter medication-assisted treatment during a year.[995] This is an important distinction because, as Dr. Alexander testified when asked about "treatment relapse or drop out," the occurrence of "relapse is an important feature of Opioid Use Disorder."[996] Likewise, Dr. Lynn O'Connell testified about retention rates at the PROACT program in Cabell County, stating, "[W]e know that abstaining and stopping opioid use and finding a life of what we define as long-term recovery often takes individuals many attempts."[997]

633. Defendants also err by assuming without evidence that an individual who has been in treatment for one year and is in remission would no longer receive any form of treatment. Dr. Alexander testified that opioid addiction "is a lifelong disorder [a]nd people, especially people that have active addiction, need long-term treatment."[998] When asked to consider a hypothetical situation similar to the one Defendants advance in their brief, Dr. Alexander responded, "I mean, we're back to the assumption because I'm not aware of recommendations that people only receive treatment for one year."[999] Relapse can also occur after someone has completed a course of treatment and is no longer receiving treatment.[1000]

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[995] Trial Tr. 5/4 (Waller) at 211(explaining the 70% figure as "if they're retained in treatment at one year, their chances of maintaining what we call short-term or long-term remission in addiction").

[996] Trial Tr. 6/28 (Alexander) at 50.

[997] Trial Tr. 6/7 (O'Connell) at 57.

[998] Trial Tr. 6/28 (Alexander) at 170; *see also id.* at 51(Dr. Alexander referring to the heightened risk of death among individuals who have discontinued treatment); Trial Tr. 6/7 (O'Connell) at 19 (Dr. O'Connell testifying that "some individuals need to be on medication assisted treatment for a year; others, five years; others, it may be a lifetime").

[999] Trial Tr. 6/28 (Alexander) at 163; *see also* Trial Tr. 6/7 (O'Connell) at 58 (Dr. O'Connell testifying: "For medication assisted treatment, the standard is that an individual should receive treatment for no less than one year.").

[1000] Trial Tr. 6/17 (Feinberg) at 150 (Dr. Feinberg noting that "Opioid Use Disorder is a chronic relapsing brain disease"); Trial Tr. 6/28 (Alexander) at 152 (Dr. Alexander referring to "someone

634. Moreover, Dr. Alexander's testimony establishes that the population of people with opioid use disorder is not static.[1001] Further, Dr. Alexander clearly rejected the assumption that underlies Defendants' math:

> Q. . . . We'd have another group of 2,500 in remission after the third year, and another group in remission of 2,500 after the fourth year, right? If we assumed an 80 percent remission –
>
> A. [by Dr. Alexander:] If you would assume that this was a static population, *but we talked about the fact that this was a dynamic population*.[1002]

635. Based on the evidence in the record, the Court finds it is reasonable to infer that of the approximately 3,000 people Dr. Alexander estimates can receive treatment for opioid use disorder at a given time, some are entering treatment for the first time, some are continuing a course of treatment from previous years, some previously entered treatment but did not complete a full course of treatment, and some had completed a full course of treatment but have relapsed.[1003]

636. Dr. Alexander calculated the number of "slots" needed for treatment, but he does not assume each person requires 365 days of treatment.[1004]

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who is living a happy, healthy life in recovery now in treatment from prescription Opioid Use Disorder who relapses").

[1001] Trial Tr. 6/28 (Alexander) at 150-151 ("Q. . . . But it's not going to be a static population over time, correct?" "A. Yes. It's a dynamic population. . . . [T]he individual people are not necessarily the same people.").

[1002] Trial Tr. 6/28 (Alexander) at 161 (emphasis added).

[1003] As such, Defendants' contention that one can calculate the number of unique people receiving OUD treatment in four years by multiplying the number of people who would receive opioid use disorder by 84% and then again by 4 is based on a series of assumptions that have no foundation in the evidence and which have been contradicted by testimony offered by Plaintiffs' well-credentialed expert witnesses. Significantly, Defendants have not offered their own expert epidemiologist to estimate the number of individuals needing treatment in Cabell/Huntington, instead choosing to rely on unfounded, back-of-the-envelope math by defense counsel.

[1004] 6/28/21 Trial Tr. (Alexander) at 89-94, 146-49, 157-60.

637. Dr. Alexander's testimony establishes that OUD treatment will save many lives and help people return to healthy, productive lives. He testified as follows:

a. OUD is a highly treatable condition.[1005]

b. Studies show that treatment greatly reduces the risk of death among opioid-addicted individuals from 5/100 person-years to 2/100 person-years.[1006]

c. Treatment makes good economic sense, with a good return on investment, and it disrupts the intergenerational cycle of addition.[1007]

d. The occurrence of relapse among some treatment patients does not undercut the effectiveness of OUD treatment.[1008]

e. Treatment is designed to minimize relapse, and a combination of approaches will reduce relapse rates.[1009]

f. Expanding the distribution of naloxone treatment has been shown to be successful in reversing overdoses in 96% of cases.[1010]

638. Medication for OUD is highly safe and effective, as Dr. Alexander testified:

a. The FDA has approved buprenorphine, methadone, and naltrexone as medication-assisted treatment ("MAT") for OUD.[1011]

b. Studies show that MAT can decrease mortality risk by as much as 50%.[1012]

[1005] 6/28/21 Trial Tr. (Alexander) at 47-48 (naloxone highly successful), 48-49 ("we have highly safe and effective medicines to treat opioid addiction").

[1006] 6/28/21 Trial Tr. (Alexander) at 51-52 this difference far exceeds that created by many FDA-approved medicines).

[1007] 6/28/21 Trial Tr. (Alexander) at 49-50 (a parent with substance use disorder is a significant risk factor for a child developing similar problems).

[1008] 6/28/21 Trial Tr. (Alexander) at 49.

[1009] 6/28/21 Trial Tr. (Alexander) at 48-49, 52.

[1010] 6/28/21 Trial Tr. (Alexander) at 58-59.

[1011] 6/28/21 Trial Tr. (Alexander) at 53.

[1012] 6/28/21 Trial Tr. (Alexander) at 53; 5/4/21 Trial Tr. (Waller) at 210-11 (MAT "decreased the mortality rate significantly" in OUD patients).

c. Individuals that are stably maintained on MAT do not have active addiction and do not develop an alternative addiction.[1013]

d. The medication helps to address cravings for opioids driven by changes in brain chemistry, cravings which otherwise keep people using opioids to feed their addiction.[1014]

e. Medication for OUD can be combined with non-pharmacologic approaches like peer coaches, 12-step programs, and vocational training. [1015]

639. The Abatement Plan treatment costs per person are based on Medicaid reimbursement rates: an average daily cost of $63.77 for outpatient-initiated care, $69.01 for intensive outpatient care, $78.15 for residential care and $78.95 for inpatient care.[1016] The treatment cost estimates account for people likely requiring less-intensive levels of care as they progress through treatment and recovery.[1017]

640. Dr. Alexander also testified that infectious diseases like hepatitis are related to opioid use and should be addressed.[1018]

641. Category 3 of the Abatement Plan, Recovery, contains five subcategories: Public Safety, Criminal Justice System, Vocational Training and Job Placement, Reengineering the Workplace, and Mental Health Counseling and Grief Support.[1019] These abatement programs are intended to help individuals with OUD and the broader Cabell and Huntington area recover from

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[1013] 5/4/21 Trial Tr. (Waller) at 210-11 (MAT did more than decrease mortality: "It actually decreased recidivism. It decreased poverty rates. It decreased sexual assault. It decreased HIV. It decreased Hepatitis C. It decreased CPS involvement.").

[1014] *See* 5/4/21 Trial Tr. (Waller) at 211 ("And they're on the medication, but they have no behaviors associated with the treatment of this that comport with the diagnosis of addiction.").

[1015] 6/28/21 Trial Tr. (Alexander) at 53-54.

[1016] 6/28/21 Trial Tr. (Alexander) at 95 (based on West Virginia reimbursement rates).

[1017] 6/28/21 Trial Tr. (Alexander) at 96.

[1018] 6/28/21 Trial Tr. (Alexander) at 29, 46.

[1019] 6/28/21 Trial Tr. (Alexander) at 29, 46.

the epidemic. The interventions as not limited to treating people with OUD. The programs include an overdose team, criminal justice programs to divert people into treatment, vocational training and job placement, programs to reengineer the workplace, and mental health counseling and grief support. The programs have been shown to be effective.[1020] For example, 82% of Cabell drug court graduates did not re-offend in the next 12 months and law enforcement-assisted diversion successfully transitions over 50% of individuals to treatment.[1021]

642. Category 4 of the Abatement Plan, Addressing Needs of Special Populations, has five subcategories: Pregnant Women, New Mothers, and Infants; Adolescents and Young Adults; Families and Children; Homeless and Housing Insecure Individuals; and Individuals with Opioid Misuse.[1022] The programs in this category address the needs of pregnant women, new mothers, the post-incarceration population, and children and families affected by the epidemic.[1023] The programs include treatment for infants with NAS and mothers, adolescents with non-medical opioid use or whose families are impacted by OUD, programs for families and children given the impact on child welfare, secure housing for homeless people, and assistance for people with opioid misuse.

643. There is great need for programs to help children and ample evidence that these programs are effective.[1024] For example:

[1020] 6/28/21 Trial Tr. (Alexander) at 60-61.

[1021] 6/28/21 Trial Tr. (Alexander) at 63-64.

[1022] 6/28/21 Trial Tr. (Alexander) at 63-64.

[1023] 6/28/21 Trial Tr. (Alexander) at 64, 69-70 ((immense body of evidence supports Plan's interventions for special populations), 71 (Plan's special populations interventions have proven successful in other jurisdictions)

[1024] 6/28/21 Trial Tr. (Alexander) at 66-70.

a. In 2017 in West Virginia, 54 out of 1,000 children were affected by the opioid epidemic compared to a national rate of 28 out of 1,000.[1025]

b. In Cabell County, up to half of the children in public schools are being raised by someone other than their parent.[1026]

c. Screening programs have been shown to reduce drug use among at-risk and medically-underserved mothers.[1027]

644. Defendants challenged Dr. Alexander's methodology in preparing the Abatement Plan, but the Court finds that his methodology was appropriate and reliable, as follows:

a. Dr. Alexander's Abatement Plan does not subtract out existing programs related to the opioid epidemic in the Cabell and Huntington Community because these funds are not certain to be available and do not cover the scope of interventions required by the Abatement Plan.[1028]

b. The Abatement Plan does not look at costs incurred by the Community to date, because the plan is forward-looking. The fact that Cabell and Huntington has not, in the past, been able to fund the full range of services required to abate the epidemic is further evidence of the need for relief, not evidence that the services are unnecessary.

c. The Abatement Plan does not differentiate between treatment of harms arising from prescription opioid use versus illicit opioid use, because there is only one opioid epidemic.[1029]

d. Similarly, the Abatement Plan does not exclude costs arising from people who have never used prescription opioids, because "there's one epidemic, not two; an opioid epidemic, not a prescription epidemic and a fentanyl and heroin epidemic." That subgroup represents a "small proportion of the entire group of people that use opioids in the community."[1030]

[1025] 6/28/21 Trial Tr. (Alexander) at 67-68.

[1026] 6/28/21 Trial Tr. (Alexander) at 67-68.

[1027] 6/28/21 Trial Tr. (Alexander) at 70-71.

[1028] Moreover, as explained elsewhere, Defendants have not shown that to the extent any abatement costs in Cabell and Huntington are currently paid for by Plaintiffs or third parties, that the existing funding sources are sustainable and that these costs should be deducted from the cost of the Abatement Plan. *See* ECF 1470 (Pltfs' Opp. to Rule 52(c) Motion on Abatement) at 36-37.

[1029] 6/28/21 Trial Tr. (Alexander) at 119-21; *see also supra*, Part I.C, III.A.3.c.

[1030] 6/28/21 Trial Tr. (Alexander) at 119-21.

e. The Abatement Plan properly encompasses people that will develop OUD in the future, because the epidemic is ongoing and at least people who are using opioids now will develop OUD in the future. The effects of opioid use, including developing OUD, can be protracted.[1031]

645. Dr. Alexander does not offer opinions on the funding sources for existing abatement programs, nor does he opine on who should pay for the Abatement Plan. Those limitations are consistent with his expertise, and not required for the Court's determination that the Plan is both necessary and appropriate.[1032]

646. Importantly, Defendants did not present an abatement plan of their own, through expert testimony or otherwise. They attempted to chip away at Plaintiffs' Abatement Plan, per above and through the testimony of Defense expert Robert Rufus,[1033] but have not offered an alternative plan for addressing the serious and apparent harms to Cabell and Huntington related to the opioid epidemic. And, as Dr. Alexander testified, the Plan itself is conservative, relying, for instance, on providing lower cost, non-in-patient treatment for the majority of individuals in treatment.[1034]

647. The Court therefore finds that Plaintiffs' proposed Abatement Plan is necessary to abate the opioid epidemic harms in Cabell and Huntington caused by Defendants' conduct.

B. The Abatement Plan's 15-Year Cost Measured in Present Value is $1,802,428,070, and in Future Value is $2,544,446,548.

648. The Plaintiffs also presented testimony from forensic economist George Barrett, who calculated the cost of the Abatement Plan. Mr. Barrett calculates economic damages as an expert witness and has testified in over 250 cases throughout West Virginia and the surrounding

[1031] 6/28/21 Trial Tr. (Alexander) at 156.

[1032] 6/28/21 Trial Tr. (Alexander) at 96-97, 120-21, 126.

[1033] *Infra*, ¶¶ 662-69.

[1034] Trial Tr. June 28, 2021 (Alexander) at 165.

region.[1035] Defendants did not challenge his qualifications and the Court accepted him as an expert in the field of forensic economics.[1036]

649. Mr. Barrett calculated the total cost of Plaintiffs' Abatement Plan, including the cost of each category, subcategory, and specific program therein. He calculated the total annual cost for each component of the Abatement Plan on a yearly basis for the 15-year duration of the Abatement Plan, beginning in the year 2021 and concluding at the end of 2035.[1037]

650. Mr. Barrett used a methodology similar to his work in other cases. He evaluated three key pieces of information: the individual items identified in the Abatement Plan, the cost of each item, and the quantity or frequency of each item.[1038] He applied the Abatement Plan as is, without modification to any of the programs or data on populations, frequency, and cost.[1039]

651. The programs in the Abatement Plan, the number of people receiving services pursuant to the Abatement Plan, and the frequency of those services were provided by Dr. Alexander.

652. The unit cost of each item in the Abatement Plan came from three experts: Mr. Barrett identified costs for wages, commercial rents, and certain local programs; Dr. Alexander

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[1035] Mr. Barrett is co-owner of Brookshire Barrett & Associates LLC, an economic consulting firm. He has testified at trial 48 times, in each case qualified as an expert. He has been hired 50-50 by plaintiffs and defendants in the last five years. He recently worked on a multi-billion-dollar class action and has worked on other large cases, including mountaintop mining. 6/29/21 Trial Tr. (Barrett) at 56-59, 63, 65, 198. Mr. Barrett received a B.A. in economics from West Virginia State University, with high honors, and an MBA in economics from Marshall University. *Id.* at 60-61. He has published articles in peer-reviewed journals, including a 2019 article on calculating economic damages in West Virginia. *Id.* at 63-64.

[1036] 6/29/21 Trial Tr. (Barrett) at 65-66, 200.

[1037] 6/29/21 Trial Tr. (Barrett) at 69-70, 83, 85.

[1038] 6/29/21 Trial Tr. (Barrett) at 66-68.

[1039] Mr. Barrett also worked closely with Dr. Alexander's team in preparing his cost calculations. 6/29/21 Trial Tr. (Barrett) at 75-76, 80.

identified medical-related costs; and Dr. Young identified costs related to child welfare.[1040] Where possible, Mr. Barrett obtained data from the local area, such as the cost of Huntington's LEAD program.[1041] He obtained wage and benefits data from the Bureau of Labor Statistics for the Huntington Metropolitan Statistical Area. Mr. Barrett's data sources are reliable, relevant to Cabell and Huntington, and similar to those he uses in other expert reports, and his methodology is consistent with that used by other forensic economists.[1042]

653. Mr. Barrett calculated the cost of the Abatement Plan for 2021, then adjusted for inflation to determine costs for the years 2022 to 2035. Average inflation rates were calculated using 30 years of past inflation data for 11 different inflation rates, corresponding to different categories of goods and services.[1043]

654. Plaintiffs presented the Abatement Plan's cost in both future value and present value. The present value is expressed in 2021 numbers, which are smaller than the future value. Present value would be relevant if the Court chose to award a lump sum to Plaintiffs.[1044] Mr. Barrett applied an interest rate of 3.73% to discount the future value to present value, based on a 30-year average of interest rates for two kinds of investments, six-month-maturing U.S. treasury bills and 10-year-maturing U.S. security treasury notes.[1045]

[1040] 6/29/21 Trial Tr. (Barrett) at 68-69. For example, data on the cost of OUD treatment came from Dr. Alexander, using Medicaid reimbursement rates, which are "very low compared to market rate." *Id.* at 73-74. 201-02.

[1041] 6/29/21 Trial Tr. (Barrett) at 70-71, 93-97, 99-100.

[1042] 6/29/21 Trial Tr. (Barrett) at 74-75, 111.

[1043] 6/29/21 Trial Tr. (Barrett) at 68-70, 83-86.

[1044] 6/29/21 Trial Tr. (Barrett) at 111-14.

[1045] 6/29/21 Trial Tr. (Barrett) at 112.

655. The Court found that Mr. Barrett is qualified as an expert in forensic economics[1046] and finds that Mr. Barrett's methodology, data sources and calculations are reliable.

656. The Court finds that Defendants have failed to meet their burden of proof, as a matter of law and fact, to show that any collateral sources should be deducted from the cost of the Abatement Plan. There is no question on this record that the current funding is unstable,[1047] and stability is necessary for epidemic response efforts to be effective.[1048] Moreover, current funding is clearly insufficient to implement the Abatement Plan and abate the opioid epidemic.[1049]

657. The Court finds that through Mr. Barrett's calculations and testimony, Plaintiffs have proven, to a reasonable degree of certainty, the total cost necessary to fund the Abatement Plan, as follows:

- The total cost of the Abatement Plan, for 2021 to 2035, in future value, is $2,544,446,548.
- The present value of the Abatement Plan, prorated from September 1, 2021 through 2035, is $1,802,428,070.

[1046] 6/29/21 Trial Tr. (Barrett) at 66.

[1047] 6/16 Trial Tr. (Young) at 36 (existing grant funding is insufficient to sustain needed family support services); Trial Tr.6/28/21 (Alexander) at 34-36 (existing community programs would not suffice to abate the opioid epidemic, based on participant interviews, wait lists, programs at or near capacity, anticipated increased demand, unstable funding, continuing deaths, addiction); Trial Tr. 7/12/21 (Colston) at 159 (testified that she has no idea what the future holds with respect to federal or state funding of Cabell and Huntington response programs).

[1048] 5/28 Tr. (O'Connell) at 36 (community needs long-term sustainable, reliable funding to make its epidemic response efforts work).

[1049] Trial Tr. 6/28 (Alexander) at 113 ("There are many programs and they, frankly, have done a remarkable job with not very much, but if you examine the magnitude of the opioid epidemic, it's clear, and I believe that I have made it clear, that much more is needed."); Trial Tr. 6/29/2021 (Barrett) at 167-168 ("Being a local economist, I can't imagine that Huntington has $1.7 billion dollars available to invest today to cover the costs of this redress model over the next 15 years.").

- The present value of the Abatement Plan, starting on January 1, 2021 through 2035, is approximately $1,890,000,000.[1050]

658. Through Mr. Barrett's testimony, Plaintiffs detailed the cost of the Abatement Plan in three different ways: 1) the total cost of the Abatement Plan *per year*, from 2021 to 2035; [1051] 2) the total cost of the Abatement Plan, over its 15-year duration, *for each subcategory* (e.g. 1A, 1B, etc.); [1052] and 3) the total cost of the Abatement Plan, over its 15-year duration, *for each individual program* in the Abatement Plan (e.g. 1A1, 1A2, etc.), providing a further level of detail.[1053] With each method, the costs specified by Mr. Barrett total $2,544,446,548.

659. The total cost of the Abatement Plan per year, from 2021 to 2035, rounded to the nearest million, is as follows:

- 2021 - $144 million
- 2022 - $149 million
- 2023 - $153 million
- 2024 - $159 million
- 2025 - $164 million
- 2026 - $159 million
- 2027 - $160 million
- 2028 - $166 million
- 2029 - $170 million
- 2030 - $174 million
- 2031 - $178 million
- 2032 - $183 million
- 2033 - $188 million
- 2034 - $192 million
- 2035 - $197 million[1054]

[1050] 6/29/21 Trial Tr. (Barrett) at 106, 115-16. Mr. Barrett calculated the costs to a reasonable degree of professional certainty. *Id.* Mr. Barrett also testified that his present value calculation resulted in a lower figure than that suggested by Defendants' expert, Mr. Rufus. *Id.* at 114.

[1051] 6/29/21 Trial Tr. (Barrett) at 104-06.

[1052] 6/29/21 Trial Tr. (Barrett) at 102-03, 106-11.

[1053] 6/29/21 Trial Tr. (Barrett) at 129-41.

[1054] 6/29/21 Trial Tr. (Barrett) at 104-06.

660. The cost for each subcategory of the Abatement Plan over the Plan's 15-year period is as follows:

- Category 1A, Prevention – Health Professional Education - $5,437,224
- Category 1B, Prevention – Patient and Public Education - $538,834
- Category 1C, Prevention – Safe Storage and Drug Disposal Programs - $35,972
- Category 1D, Prevention – Community Prevention and Resiliency - $17,924,519
- Category 1E, Prevention – Harm Reduction - $5,544,455
- Category 1F, Prevention – Surveillance, Education, and Leadership - $3,275,608
- Category 2A, Treatment – Connecting Individuals to Care - $26,674,357
- Category 2B, Treatment – Treating Opioid Use Disorder - $1,705,896,182
- Category 2C, Treatment – Managing Complications - $301,682,032
- Category 2D, Treatment – Expanding the Healthcare Workforce - $6,185,398
- Category 2E, Treatment – Distributing Naloxone and Providing Training - $10,377,665
- Category 3A, Recovery – Public Safety - $11,623,562
- Category 3B, Recovery – Criminal Justice System - $42,051,138
- Category 3C, Recovery – Vocational Training and Job Placement - $41,912,512
- Category 3D, Recovery – Reengineering the Workplace – no designated costs
- Category 3E, Recovery – Mental Health Counseling and Grief Support - $3,651,622
- Category 4A, Addressing Needs for Special Populations – Pregnant Women, New Mothers, and Infants - $95,700,232
- Category 4B, Addressing Needs for Special Populations – Adolescents and Young Adults- $33,990,116
- Category 4C, Addressing Needs for Special Populations – Families and Children - $212,040,134
- Category 4D, Addressing Needs for Special Populations – Homeless and Housing Insecure Individuals - $3,941,041
- Category 4E, Addressing Needs for Special Populations –Individuals With Opioid Misuse – no specific costs for this category.[1055]

661. The cost of the Abatement Plan far surpasses the City and County's ability to pay. The combined city and county budgets are only $87 million,[1056] so given the $2,544,446,548 cost

[1055] 6/29/21 Trial Tr. (Barrett) at 102-03, 106-11.

[1056] *See* 6/29/21 Trial Tr. (Barrett) at 205; *see also* 6/30/21 Trial Tr. (Williams) at 28 (Huntington has $55 million budget).

of the Abatement Plan, it would take roughly 29 years to pay for the plan if the budgets were devoted to nothing else.[1057]

662. Defendants' expert Robert Rufus responded to Dr. Alexander and Mr. Barrett's testimony, but Mr. Rufus's testimony was of limited or no relevance to the Court, for several reasons.

663. First, he lacks equivalent expertise to Dr. Alexander and Mr. Barrett. Mr. Rufus is a certified public accountant, not an economist, epidemiologist, or public-health expert. Outside of this case, his work includes tax work, management consulting, and mergers and acquisitions. He was qualified as an expert in "public and forensic accounting" only.[1058]

664. Second, his testimony was narrow. Mr. Rufus did not create an alternative to the Abatement Plan. He did not criticize specific programs in the Abatement Plan, other than OUD treatment. He did not challenge the 15-year duration of the plan. He did not dispute Mr. Barrett's methodology for calculating the Abatement Plan's cost, nor challenge Mr. Barrett's math.[1059] Mr. Rufus provided no opinion on whether the Abatement Plan's programs are necessary, nor the medical judgments underlying Dr. Alexander's opinions, nor the capacity or effectiveness of existing abatement programs in Cabell and Huntington.[1060]

[1057] As Mr. Barrett testified, "Being a local economist, I can't imagine that Huntington has $1.7 billion dollars available to invest today to cover the costs of this [Abatement Plan] over the next 15 years." 6/29/21 Trial Tr. (Barrett) at 167-68.

[1058] 6/29/21 Trial Tr. (Barrett) at 8-10, 12.

[1059] *See generally* 6/29/21 Trial Tr. (Barrett) at 167-68; 7/12/21 Trial Tr. (Rufus) at 8-10, 12.

[1060] 7/12 Trial Tr. (Rufus) at 8-10, 12.

665. Mr. Rufus agreed that current spending on abatement in Cabell and Huntington is a fraction of what Plaintiffs are seeking in the Abatement Plan, and said it is "probably true" that current abatement spending is less than what is needed.[1061]

666. Mr. Rufus identified current abatement programs and spending by the City, County, and third parties. He identified grant funding but agreed that such funds are not guaranteed.[1062]

667. The Court finds that the funding sources identified by Mr. Rufus are collateral sources and should not be deducted from the cost of the Abatement Plan. The Court further finds that Defendants have not met their burden to show that such collateral sources should be deducted from the cost of the Abatement Plan.[1063]

668. At trial, for the first time, Mr. Rufus offered an alternate calculation of OUD treatment costs. Mr. Barrett calculated that the Abatement Plan's treatment programs would cost $1,705,896,182 over the 15-year duration of the plan. Mr. Rufus argued that treatment costs should be $1,061,849,848 lower, i.e., roughly $644 million in total, based on his recalculation of patients' treatment period. Mr. Rufus agreed that "if the Judge agreed with your number, [Plaintiffs would] get $644 million [for treatment]. If the Judge agrees with Dr. Alexander and Mr. Barrett, it's $1.7 billion [for treatment], or the number could be anywhere in between?"[1064]

669. The Court finds that the calculation of treatment costs by Dr. Alexander and Mr. Barrett is more reliable than the recalculation by Mr. Rufus, who lacks expertise, and thus $1,705,896,182 is the accurate figure for the Abatement Plan's treatment costs.

[1061] 7/12/21 Trial Tr. (Rufus) at 16-17, 51.

[1062] 7/12/21 Trial Tr. (Rufus) at 28 ("[B]ut grant money is not guaranteed. That's a fact.").

[1063] 7/12/21 Trial Tr. (Rufus) at 20-28.

[1064] 7/12/21 Trial Tr. (Rufus) at 52-55.

* * * *

670. The Court its closes findings of fact with with Dr. Alexander's conclusion regarding the Abatement Plan:

> This is not a moonshot. This is not something that is beyond the capability of this community. But it will take hard work, and it will take resources, and it will take coordination and planning such that I speak to in the materials that I've provided. I think if the -- Cabell County and the City of Huntington implement this plan, I think that they have every reason to look forward to many, many good years ahead and I believe that there's not a moment to lose. [1065]

[1065] 6/28/21 Trial Tr. (Alexander) at 114:11-19.

CONCLUSIONS OF LAW

Based upon its findings of fact, the Court adopts the following conclusions of law:

I. Jurisdiction and Venue.

1. The claims against Defendants other than AmerisourceBergen, Cardinal, and McKesson were severed prior to this case being remanded from MDL 2804.[1066] Plaintiffs' sole claim in this action is the abatement of a public nuisance.

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 as the Plaintiffs are both citizens of the State of West Virginia and all of the Defendants are citizens of states other than West Virginia and the amount in controversy exceeds $75,000 exclusive of interest and costs.

3. Venue is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in the Southern District of West Virginia.

II. Plaintiffs Have Standing and to Bring this Action Seeking to Abate a Public Nuisance.

4. The West Virginia Legislature has granted Plaintiffs express statutory authority to "abate or cause to be abated" a public nuisance.[1067] The Supreme Court of Appeals long ago recognized the right of municipalities to seek enforcement of this statutory authority by bringing an abatement action in court where the question of whether the condition was a nuisance is a question of fact.[1068]

[1066] Doc. 123.

[1067] W.Va. Code § 8-12-5 (13), (23), and (44); W.Va. Code § 7-1-3kk.

[1068] *Sharon Steel Corp. v. City of Fairmont*, 175 W.Va. 479, 488, 334 S.E.2d 616, 625 (1985) (prior to abating a condition that a municipality declares as a public nuisance, municipality must first "prosecut[e] the matter in a court").

5. The Defendants previously moved for summary judgment on the basis that the Plaintiffs lacked standing.[1069] This Court rejected Defendants' claim that West Virginia law granted municipal standing to abate a nuisance only when there was an allegation that the conduct was a nuisance per se or a nuisance under a specific municipal ordinance.[1070] Instead, this Court found that a municipality has standing to invoke its general power to "abate or cause to be abated" a public nuisance and seek judicial redress to abate something alleged to be a common law public nuisance.[1071] Plaintiffs' claims at trial that Defendants' distribution of opioids constituted an unreasonable interference and constitutes precisely the kind of common law public nuisance for which Plaintiffs are granted standing to abate under *Sharon Steel, supra*.[1072]

6. Alternatively, the Court found that Plaintiffs' allegations that Defendants were engaged in illegal conduct in relation to their distribution of opioids, if proved, would constitute a nuisance per se which would confer standing.[1073] Under the Restatement (Second) of Torts,[1074]

[1069] Doc. 238.

[1070] *Id.*

[1071] Doc. 1248 at 11-14.

[1072] *See also* Restatement (Second) of Torts § 821B(2)(a) (1979) ("Second Restatement") ("significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience may support a finding of public nuisance.").

[1073] Doc. 1248 at 18.

[1074] The Court in *Duff v. Morgantown Energy Associates (M.E.A.)* equated its definition of public nuisance with the Second Restatement's definition. 187 W.Va. 712, 716, n.6, 421 S.E.2d 253, 257, n. 6 (1992) (characterizing its definition as "consistent with" Restatement (Second) of Torts § 821B (1979)); *see also Rhodes v. E.I. du Pont de Nemours and Company*, 657 F.Supp.2d 751, 768 (S.D. W.Va. 2009) (West Virginia's definition of nuisance is "consistent with the Restatement (Second) of Torts § 821B(1).") (citing *Duff, supra*)); *Sharon Steel Corp.*, 175 W. Va. at 483, 334 S.E.2d at 620 (citing Second Restatement § 821B); *see also State ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, No. 12-C-141, 2014 WL 12814021, at *9 (W. Va. Cir. Ct. Dec. 12, 2014); *Barker v. Naik,* No. 2:17-CV-04387, 2018 WL 3824376, at *3 (S.D.W. Va. Aug. 10, 2018); *see also Callihan v. Surnaik Holdings of WV, LLC*, No. 2:17-CV-04386, 2018 WL 6313012, at *5 (S.D.W. Va. Dec. 3, 2018).

illegal conduct constitutes an unreasonable interference sufficient to constitute a public nuisance.[1075] Other authorities agree,[1076] and it has long been the law in this State that engaging in any form of business in defiance of laws regulating or prohibiting business activities constitutes a nuisance per se.[1077]

7. Defendants emphasize that the distribution of drugs is a legal activity. However, here, "the relevant conduct is the alleged violations of law in connection with Defendants' distribution of pharmaceutical drugs, not the lawful business of pharmaceutical drug distribution in general."[1078]

8. The Court incorporates its previously issued rulings and confirms that both Plaintiffs have standing to bring their claims to abate a public nuisance against the Defendants – either as a common-law nuisance or a nuisance per-se.[1079]

[1075]Second Restatement § 821B(2)(c); *Cincinnati v. Beretta U.S.A. Corp.*, 2002-Ohio-2480, ¶ 8, 95 Ohio St. 3d 416, 418–19, 768 N.E.2d 1136, 1142 (Ohio 2002) ("Unreasonable interference" under section 821B includes "conduct that is contrary to a statute, ordinance, or regulation").

[1076] 66 C.J.S. Nuisances § 4 (absolute or per se nuisance includes "an act involving culpable *and unlawful conduct* causing unintentional harm" (emphasis added)); 58 Am. Jur. 2d Nuisances § 1 ("Nuisance is generally applied to that class of wrongs that arises from the unreasonable, unwarrantable, *or unlawful use* (emphasis added)); *City of Cincinnati*, 95 Ohio St. 3d at 419–21, 768 N.E.2d at 1142–43 (With an absolute nuisance, the wrongful act is either intentional or unlawful and strict liability attaches notwithstanding the absence of fault because of the hazards involved). Even when the conduct is not expressly in violation of the law, it can still constitute an absolute nuisance or a nuisance per se "because of the hazards involved." 66 C.J.S. Nuisances § 4. The massive distribution of highly addictive controlled substances would certainly fall into this category.

[1077] *Princeton Power Co. v. Calloway*, 99 W. Va. 157, 128 S.E. 89, 92 (1925).

[1078] Doc. 1248 at 14.

[1079] Doc. 1248-0 at p. 11 (common law nuisance) and p. 18 (nuisance per se).

III. Plaintiffs' Public Nuisance Claims Implicate Public Rights.

9. Under West Virginia law, a public nuisance is "an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons" and "this definition is consistent with the Second Restatement, which defines a public nuisance as 'an unreasonable interference with a right common to the general public.'"[1080]

10. The Second Restatement identifies, as one example of an unreasonable interference with public rights, conduct that "involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience."[1081]

11. West Virginia case law confirms the role of public nuisance actions in addressing harms to the public health and safety.[1082]

A. Defendants' Conduct Constitutes Interference with Public Rights.

12. The Court finds that Plaintiffs have proven that the opioid epidemic in Cabell and Huntington is a significant interference with rights common to the general public: the rights to the health and safety of the community at large. If the interest invaded "is an interest shared equally by members of the public, then the alleged nuisance is public in nature."[1083] The fact that an

[1080] *Duff*, 187 W. Va. at 716, 421 S.E.2d at 257 and n.6 (quoting Second Restatement).

[1081] Second Restatement, § 821B(2)(a) (1979).

[1082] *See, e.g.*, *State ex rel. Smith v. Kermit Lumber & Pressure Treating Co.*, 200 W. Va. 221, 245, 488 S.E.2d 901, 925 (1997) ("A public nuisance action usually seeks to have some harm which affects the public health and safety abated."); *see also Rhodes,* 657 F.Supp.2d at 768 (citing Second Restatement, § 821B cmt. b for the point that "conduct interfering with the public health constitutes a public nuisance").

[1083] *Rhodes,* 636 F.3d at 96.

interference with a public right will invariably affect individual members of the public does not change the nature of the right.[1084]

13. The Court rejects Defendants' claim that the rights implicated by the opioid epidemic are a collection of individual rights rather than rights common to the general public. In the MDL, Judge Polster has repeatedly rejected the same arguments by these and other defendants.[1085] Noting the plaintiffs' evidence of increased opioid-related overdoses, hospital admissions, foster-care placements, and arrests, Judge Polster held that "[a] factfinder could reasonably conclude that this evidence demonstrates an interference with public health and public safety rights."[1086] In so holding, Judge Polster applied Ohio law which, like the law in West Virginia, follows Section 821B of the Second Restatement.[1087]

14. Likewise, West Virginia state courts have repeatedly concluded that the opioid epidemic constitutes an interference with public rights based upon the epidemic's impact on West Virginia communities.[1088]

[1084] *Id.* (explaining that, where the defendant's conduct "interfered with the general public's access to clean drinking water," "[t]he fact that the water eventually was pumped into private homes did not transform the right interfered with from a public right to a private right").

[1085] *In re Nat'l Prescription Opiate Litig.*, 406 F. Supp. 3d 672, 674 (N.D. Ohio 2019) ("The Court has previously rejected arguments that: (i) Plaintiffs' claims rely on an aggregation of individual rights, as opposed to rights commonly held by the public; and (ii) none of the allegedly interfered-with rights constitute public rights.").

[1086] *Id.*

[1087] *See id.* (quoting *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1142 (Ohio 2002) ("'A public nuisance is an unreasonable interference with a right common to the general public,' and unreasonable interference includes acts that 'significantly interfere with public health, safety, peace, comfort or convenience'") (quoting 4 Restatement of the Law 2d, Torts (1965), § 821B(1)-(2)).

[1088] *See Brooke Cty. Comm'n v. Purdue Pharma, L.P.*, No. 17-C-248, p. 13 (W. Va. Marshall Cty. Cir. Ct. Dec. 28, 2018) ("The Court further finds and concludes that Plaintiffs have adequately alleged that Defendants interfered with a public right."), *writ denied*, *State ex rel. Cardinal Health, Inc. v. Hummel*, No. 19-0210 (W. Va. June 4, 2019); *State ex rel. Morrisey v. AmerisourceBergen*

15. The Court finds that Defendants' reliance on out-of-state authorities is unpersuasive.[1089] As the Plaintiffs have pointed out, courts in twenty-six states have rejected the Defendants' claim that no public rights are at issue in these opioid cases.[1090] And, recent decisions accepting similar public nuisance claims in non-opioid contexts confirm that these kinds of public health harms can constitute an interference with a public right.[1091] The weight of these decisions has pushed the question of whether an opioid epidemic constitutes an interference with public rights well past the tipping point – with at least one state court reversing its prior rejection of an opioid-based public nuisance claim.[1092]

16. The Court rejects the Defendants' attempt to frame the harms of the opioid epidemic as only affecting individuals struggling with addiction or those who have overdosed. All members of the community are affected by the devastation.

Drug Corp., No. 12-C-141, 2014 WL 12814021, at *10 (W. Va. Boone Cty. Cir. Ct. Dec. 12, 2014), (concluding that "the State's public nuisance claim sufficiently alleges the safety and health and morals of the people of West Virginia has been compromised due to Defendants' alleged wrongful influx of addictive, controlled substances into West Virginia, thereby causing substantial injury to West Virginia citizens and taxpayers"), *writ denied*, *State ex. rel. AmerisourceBergen Drug Corp. v. Thompson*, No. 15-1026 (W. Va. Jan. 5, 2016); *see also Monongalia County, et al. v. Purdue Pharma L.P.*, et al., Nos. 18-C-222-236 (adopting and applying the reasoning and rulings from *Brooke County*), *writ denied*, *State ex rel. AmerisourceBergen Drug Corp. v. Moats,* No. 19-1051 (W.Va. January 30, 2020).

[1089] *See* Nuisance Motion for Summary Judgment at 11 (Doc. 1004) (citing *State v. Lead Industries Association*, 951 A.2d 428 (R.I. 2008) and *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004)).

[1090] See Doc. 1290-1 (Plaintiffs' Appendix of Decisions).

[1091] *See, e.g., In re JUUL Labs, Inc., Mktg., Sales Practices, & Prod. Liab. Litig.,* No. 19-MD-02913-WHO, 2020 WL 6271173, *63 (N.D. Cal. Oct. 23, 2020) (claims by school boards that manufacturer of electronic cigarettes interfered with public health stated a claim for interference with public rights sufficient to support a claim for public nuisance under laws of Arizona, New York, Pennsylvania, Florida, and California).

[1092] *See Michigan ex rel. Kessel v. Cardinal Health, Inc.*, No. 19-016896-NZ, slip op. (Cir. Ct. Mar. 24, 2021), *reversing on reconsideration* slip. op. (Cir. Ct. Nov. 17, 2020).

17. The Court has detailed above the horrific consequences to Plaintiffs' communities.[1093] Over 8,000 people in Cabell County have opioid use disorder.[1094] There have been over 1,000 opioid deaths.[1095] Approximately 2,500 babies were born with NAS.[1096] The epidemic has led to separation of families and children.[1097] The epidemic has increased the spread of infectious disease, including HIV, Hepatitis B and C, and complications due to Endocarditis.[1098] The epidemic has resulted in incarcerations,[1099] crime,[1100] drug trafficking,[1101] and a diversion of City and County resources from other governmental functions to the opioid epidemic.[1102]

18. The impact of the opioid epidemic on the Cabell Huntington Community at large will be long-lasting, as a generation of children carry its burdens for years, with corresponding impact on educators and caregivers.[1103] Indeed, the harms from the epidemic are intergenerational addiction is passed on to subsequent generations.[1104]

19. The testimony and evidence presented demonstrates Plaintiffs are not seeking to vindicate private rights, nor are they arguing that the opioid epidemic interferes with a public right simply because it affects a large number of individuals (though it does). Plaintiffs have established

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[1093] *See* FOF, ¶¶ 4-104.

[1094] FOF, ¶ 43.

[1095] FOF, ¶ 53.

[1096] FOF, ¶ 67.

[1097] FOF, ¶¶ 61-68.

[1098] FOF, ¶¶ 69-79.

[1099] FOF, ¶¶ 80-87.

[1100] *Id.*

[1101] *Id.*

[1102] *Id.*

[1103] FOF ¶ 68.

[1104] FOF ¶¶ 67, 521.

that the opioid epidemic harmed businesses and economic development in the community. Entire neighborhoods have been devastated with homes burnt out and abandoned.[1105] The daily presence of people suffering from OUD in the community resulted in residents avoiding the Huntington businesses because of fear of encountering homeless addicts.[1106] It has resulted in community members being regularly hindered in their ability to occupy, use, and enjoy public spaces.[1107]

20. The Court concludes that the opioid epidemic in Cabell County and the City of Huntington meets the Second Restatement's definition of a public nuisance in that the epidemic is an unreasonable, significant, long-lasting, and continuing interference with the public health, public safety, public peace, public comfort, and public convenience of the County and City's communities.

B. West Virginia Public Nuisance Law Is Not Limited to Interference with Public Property or Resources.

21. The Court rejects the Defendants argument that West Virginia public nuisance law is limited to interference with public property or resources.

22. Under West Virginia law, "nuisance is a flexible area of the law that is adaptable to a wide variety of factual situations."[1108]

23. Defendants cite no authority supporting their interpretation of *Sharon Steel*'s statement regarding flexibility as confined to a category of injury involving public property or resources.

[1105] FOF ¶ 84.

[1106] FOF ¶ 84.

[1107] FOF ¶ 84-85.

[1108] *Sharon Steel Corp.*, 175 W. Va. at 483-84, 334 S.E.2d at 621.

24. West Virginia cases have rejected this purported limitation. In *Kermit Lumber*, the Supreme Court of Appeals noted that "[t]he term 'public nuisance' does not have an exact definition[,]" but that, "[g]enerally, it has been described as 'the doing of or the failure to do something that injuriously affects the safety, health, or morals of the public, or works some substantial annoyance, inconvenience, or injury to the public[.]'"[1109]

25. A number of other courts adjudicating opioid cases, based either on West Virginia law,[1110] or the law of other states, have rejected this limitation on public nuisance claims.[1111] The Court is persuaded that these decisions correctly articulate the substance of West Virginia law.

[1109] *Kermit Lumber*, 200 W. Va. at 245 n.28 (quoting 58 Am.Jur.2d Nuisances § 35 (1989)).

[1110] *Morrisey*, 2014 WL 12814021 at *9 (citing *Kermit Lumber*, 200 W. Va. at 245 n. 28 and holding that State of West Virginia's claims against opioid distributors "fit squarely" within this definition of public nuisance); *Brooke Cty. Comm'n* at p. 13 ("a claim for public nuisance is not limited to property disputes and that West Virginia courts have applied the public nuisance doctrine in numerous contexts, including in opioids cases like this."); *see also Lemongello v. Will Co.*, No. CIV.A. 02-C-2952, 2003 WL 21488208, at *2 (W. Va. Cir. Ct. June 19, 2003) (holding, in case alleging that the defendants' sale of handguns supplied an illegal handgun market, that "West Virginia law does not limit claims of public nuisance to those dealing with real property").

[1111] *See People of the State of California, acting by and through Santa Clara County Counsel Orry P. Korb and Orange County District Attorney Tony Rackauckas v. Purdue Pharma L.P. et al*, Case No. 30-2014-00725287-CU-BT-CXC, (Orange County Superior Court March 13, 2021)(denying motion for summary judgment on public nuisance); *State of Ohio, ex rel. Dewine v. Purdue Pharma L.P.*, No. 17 CI 261, 2018 WL 4080052, at *4 (Ohio Ct. Com. Pl. Aug. 22, 2018) (holding that Ohio "adequately pled public nuisance" and interference with a public right); *State of Vermont v. Purdue Pharma L.P.*, No. 757-9-18, slip op. at 4-6 (Vt. Sup. Ct. March 18, 2019) (rejecting Defendants' arguments that the State failed to allege interference with any public right); *Commonwealth of Kentucky ex rel. Beshear v. Cardinal Health LLC*, No. 18-CI-00I013, slip op. at 24-28 (Ky. Cir. Ct. Sept. 12, 2019) (rejecting Cardinal's arguments that the Commonwealth failed to adequately plead interference with a public right); and *Morrisey* 2014 WL 12814021 at *9 and *Morrisey v. Cardinal Health, Inc.*, No. 12-C-140, slip op. (Cir. Ct. Apr. 17, 2015), writ denied *State ex. rel. AmerisourceBergen Drug Corp. v. Thompson*, No. 15-1026 (W.Va. Jan 5, 2016).

C. Plaintiffs' Claims are Not Excluded from Nuisance Law Because They Arise from the Distribution of Products.

26. The Court predicts that the West Virginia Supreme Court of Appeals would reject Defendants' argument that public nuisance claims cannot involve the distribution and subsequent use or misuse of a product. West Virginia trial courts have upheld public nuisance claims involving the distribution and subsequent use of products, including firearms and opioids.[1112] These uniform trial court decisions, along with the repeated denials of review by the Supreme Court of Appeals, provide persuasive guidance as to how the Supreme Court of Appeals would rule on Defendants' arguments here.

27. There is no exception to public nuisance law for claims involving products when the use or distribution of those products creates an unreasonable interference with a public right. Defendants' arguments to the contrary are "based upon an entirely mistaken emphasis upon what the defendant has done rather than the result which has followed."[1113]

[1112] *See Lemongello*, 2003 WL 21488208; *Morrisey*, 2014 WL 12814021; *Brooke Cty. Comm'n*, *supra*. Contrary to Defendants' argument that West Virginia's high court would reject such claims, the Supreme Court of Appeals has on multiple occasions denied review of trial court decisions upholding public nuisance claims based on the distribution of opioids. *See State ex. rel. AmerisourceBergen Drug Corp. v. Thompson*, No. 15-1026 (W. Va. Jan. 5, 2016); *State ex rel. AmerisourceBergen Drug Corp. v. Hummel*, No. 19-0210 (W. Va. June 4, 2019). In addition, the court in *In re: Opioid Litigation*, No. 19-C-19000 (Kanawha Cty. Cir. Ct. Oct. 9, 2019), considering similar arguments to dismiss claims based on harms from the opioid epidemic, adopted and applied the reasoning and rulings from *Brooke County Commission*, and the Supreme Court of Appeals again denied review. *See State ex rel. AmerisourceBergen Drug Corp. v. Moats*, No. 19-1051 (W. Va. Jan. 30, 2020).

[1113] *Commonwealth v. Barnes & Tucker Co.*, 319 A.2d 871, 883 (Pa. 1974) (quoting William L. Prosser, *Handbook of the Law of Torts* § 88 at 595 (3d ed. 1964)). The term "nuisance" refers "to the interests invaded, to the damage or harm inflicted, and not to any particular kind of act or omission which has led to the invasion." William L. Prosser, *Handbook of the Law of Torts* § 87 (4th ed. 1971). And while Defendants argue that "most high courts across the country" have not applied public nuisance law to claims involving products, Nuisance MSJ at 5, multiple state supreme courts have upheld product-based nuisance claims in the context of handguns, *see, e.g.*, *City of Cincinnati*, 768 N.E.2d 1136; *City of Gary ex rel. King v. Smith & Wesson Corp.*, 801

28. In particular, relying on reasoning that is directly applicable here, courts have upheld public nuisance claims where the creation or maintenance of an illicit market for a product due to oversupply gives rise to a public nuisance.[1114]

29. The Defendants' argument further fails as it relies heavily on a provision of the Third Restatement, not West Virginia law.[1115] While West Virginia courts (including the Supreme Court of Appeals) have cited Section 821B of the Second Restatement with approval and noted its consistency with West Virginia law, no West Virginia court has adopted Section 8 of the Third Restatement. Defendants have not provided any examples of West Virginia state courts citing this section, or any other state courts for that matter.[1116] No state's highest court has adopted Section

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N.E.2d 1222, 1229-33 (Ind. 2003); *People ex rel. Gallo v. Acuna*, 929 P.2d 596 (Cal. 1997), while numerous other courts have recognized public nuisance claims involving products including lead paint, "flushable" wipes, gasoline additives, and opioids. *See, e.g.*, *People v. ConAgra Grocery Prods. Co.*, 227 Cal. Rptr. 3d 499, 546 (Cal. Ct. App. 2017) (lead paint); *City of Wyoming v. Procter & Gamble Co.*, 210 F. Supp. 3d 1137, 1162 (D. Minn. 2016) ("flushable" wipes); *State of Maryland v. Exxon Mobil Corp.*, 406 F. Supp. 3d 420 (D. Md. 2019) (MTBE); *City of Boston v. Purdue Pharma, L.P.*, No. 1884CV02860, 2020 WL 977056 (Mass. Super. Ct. Jan. 31, 2020) (distribution of opioids); *In re Opioid Litig.*, 2018 WL 3115102 (N.Y. Sup. Ct. June 18, 2018) (opioids); *Gov't of U.S. Virgin Islands v. Takata Corp.*, No. ST-16-CV-286, 2017 WL 3390594, at *40-44 (V.I. Super. Ct. June 19, 2017) (airbags).

[1114] *See Ileto v. Glock Inc.*, 349 F.3d 1191, 1214 (9th Cir. 2003) (recognizing public nuisance claims based on the defendants "purposefully over-saturating the legal gun market in order to take advantage of re-sales to distributors that they know or should know will in turn sell to illegal buyers"); *City of New York v. Beretta U.S.A. Corp.*, 315 F. Supp. 2d 256, 276 (E.D.N.Y. 2004) ("Under New York law, a claim for public nuisance may lie against members of the gun industry whose marketing and sales practice lead to the diversion of large numbers of firearms into the illegal secondary gun market.").

[1115] *See* Nuisance MSJ (Doc 1004) at 6-7 (relying on § 8 of the Restatement (Third) of Torts: Liab. for Econ. Harm (comment g)).

[1116] Generally, the Third Restatement has been viewed as a radical departure from the settled standards of tort law. *See* Restatement (Third) of Torts: Liab. for Econ. Harm, Introduction, Pg. 3 ("This Restatement is, therefore, an almost total overhaul of Restatement Second as it concerns the liability of commercial sellers of products."). Unlike its predecessor, the Third Restatement has not been widely adopted by the states. *See, e.g.*, *Delaney v. Deere and Co.*, 999 P.2d 930, 946 (Kan. 2000) (stating that the (Third) Restatement "goes beyond the law" and is "contrary to the

8, and this Court is reluctant to presume that West Virginia would do so if presented with the question.

30. In any event, by its express terms, Section 8 of the Third Restatement does not apply to the Plaintiffs' abatement claim here. The provision applies only to claims for economic loss by a private party who has suffered an injury "distinct in kind from those suffered by members of the affected community in general."[1117] The comment to Section 8 makes clear that the provision is not intended to apply to public nuisance actions brought by public officials.[1118]

31. Here, the Supreme Court of Appeals' explanation that West Virginia's definition of public nuisance is consistent with Section 821B of the Second Restatement, together with its repeated denial of review of trial court rulings upholding public nuisance claims involving the distribution and subsequent use of products, offer clear guidance on the state law. West Virginia law provides a broad and flexible definition of public nuisance—one that fully encompasses Plaintiffs' claims here.

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law in Kansas"); *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 415 (Pa. 2014) (declining to adopt a product liability portion of the Third Restatement and discussing other courts across the country that have done the same); *Potter v. Chicago Pneumatic Tool Co.*, 694 A.2d 1319, 1331 (Conn. 1997) (observing that a provision of the Draft Restatement (Third) "has been a source of substantial controversy among commentators" and stating that rule promulgated in the Draft Restatement (Third) was inconsistent with the court's "independent review of the prevailing common law").

[1117] Restatement (Third) of Torts: Liab. for Econ. Harm, § 8.

[1118] *Id.*, § 8 cmt. a ("In addition to the common-law claims recognized here, public officials may bring civil or criminal actions against a defendant who creates a public nuisance. . .. The definition of 'public nuisance' for those purposes is widely a matter of statute and tends to be considerably broader than the common-law definition recognized by this Section as a basis for a private suit.").

IV. Defendants' Conduct Constituted an Unreasonable Interference with a Public Right.

32. West Virginia has adopted the definition of "public nuisance" set forth in § 821B of the Second Restatement:[1119] "A public nuisance is an unreasonable interference with a right common to the general public."[1120] Thus, in West Virginia, the touchstone of public nuisance liability is unreasonableness.[1121]

33. The Second Restatement offers the following guidance:

> Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:
>
> > (i) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or
> > (ii) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or
> > (iii) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.[1122]

[1119] COL, *supra,* ¶ 6, n. 9.

[1120] Second Restatement, § 821B(1) (1979).

[1121] *See, e.g., Duff*, 421 S.E.2d at 262 (reasonableness of conduct determines whether conduct constitutes a nuisance); *West v. National Mines Corp*., 168 W.Va. 578, 587, 285 S.E.2d 670, 677 (W. Va. 1981), *reh'g on appeal*, 336 S.E.2d 190 (W. Va. 1985) (activity must be reasonable to avoid liability for nuisance).

[1122] Second Restatement, § 821B(2).

34. This Court has previously recognized that "unreasonableness" is the applicable standard.[1123] As set forth in detail in the findings above, the evidence at trial established that Plaintiffs have met this burden.[1124]

35. The Court emphasizes that the conduct in question is the distribution of dangerously addictive narcotics with a high risk of diversion. Distributors like Defendants are uniquely able to act to prevent diversion because they know the quantity of opioids they are shipping to their customers within a particular region and can observe patterns of excessive or unusual ordering indicative of diversion at the pharmacies they supply. Nonetheless, Defendants acted unreasonably in failing to control the supply of opioids into Cabell and Huntington and failing to take reasonable steps to prevent diversion of these dangerous drugs.

36. Defendants acted unreasonably when they distributed an unusually excessive quantity of opioids into Cabell and Huntington taking account the size of the population of the area into which these drugs were shipped and the scourge of addiction that was emerging.

[1123] *See* April 29, 2021 Memorandum Opinion and Order, Dkt. 1294 at 6 (finding "Defendants have not established that there is a 'fault' element (in the way they describe it [intent, recklessness, or negligence]) of a public nuisance claim under West Virginia law."); *id.* ("The court agrees with plaintiffs that because defendants' motion does not establish the reasonableness of defendants' conduct, the motion should be denied.").

[1124] Even assuming *arguendo* that the Defendants are correct that an element of "fault" is required to prove the unreasonableness of their conduct, Dkt. 1294 at 6, the Court concludes that Plaintiffs have met the requirement as Defendants' conduct was intentional. In denying the Defendants' motions for summary judgment pertaining to fault, this Court held that "even assuming that there is a culpability ("fault") element in the public nuisance context, the motion should still be denied because there are disputed issues of material fact about whether defendants' conduct was intentional." Dkt. 1294 at 6. As the Court previously held, Plaintiffs are not required to prove *mens rea* – or intent to create the opioid crisis or the resulting harms – only that their actions were intentional. Dkt. 1294 at 5-6. Here, as set forth below, the Plaintiffs proved that Defendants' conduct was an unreasonable interference based on its intentional selling and shipment of high volumes of opioids into Cabell and Huntington, shipping suspicious orders without conducting due diligence, failing to implement the due diligence programs, distributing unreasonable quantities of opioids, failing to upgrade ineffective due diligence programs, and violating the CSA and the WVCSA.

37. Defendants also acted unreasonably in operating their SOMs programs.

38. Finally, Defendants acted unreasonably with respect to the distribution of opioids when they failed to comply with the requirements of the CSA.

A. The Volume of Pills Shipped to Cabell and Huntington and Surrounding Areas Proves Unreasonable Conduct.

39. The Court concludes that Defendants' distribution of an extraordinarily disproportionate quantity of opioids into Cabell and Huntington was unreasonable. Despite Defendants' diversion control teams' knowledge of the opioid crisis, opioid addiction, and the relationship between pain pills and heroin, each of the Defendants distributed increasingly large amounts of opioids into Cabell and Huntington and the surrounding areas creating long lasting consequences that continue to interfere with the public rights identified above. As this conduct produced a long-lasting effect that Defendants knew or hadreason to know had a significant effect upon the public right, it constitutes unreasonable conduct under the Second Restatement test.[1125]

40. For example, ABDC distributed a total of 36 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell and Huntington. Between June of 2002 and December of 2018, the equivalent of 360 doses for every man, woman, and child in the community, an amount that was, in and of itself, unreasonable and could not be explained by changes in the standard of care for treating pain.[1126]

41. In January 2006, ABDC's hydrocodone shipments to West Virginia doubled the national per pharmacy average.[1127] From 2005 to 2016, ABDC shipped 248.16 million dosage

[1125] Second Restatement, § 821B(2)(iii).

[1126] FOF, ¶ 174.

[1127] FOF, ¶ 175

units of oxycontin and hydrocodone to West Virginia.[1128] From 2007 through 2018, there were 77,398 transactions by ABDC with pharmacies in Cabell and Huntington.[1129]

42. Cardinal distributed over 37 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell and Huntington, between January 1996 and May 2018, the equivalent of 370 doses for every man, woman, and child in the community, an amount that was, in and of itself, unreasonable and could not be explained by changes in the standard of care for treating pain.[1130] Between 2006 and 2014, Cardinal's monthly average shipments of opioids were well in excess of national averages.[1131]

43. While McKesson distributed 7.725 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell and Huntington, between January 2004 and May 2018.[1132] While this number was smaller than Cardinal and ABDC, shipments to the few pharmacies it did serve were clearly excessive in that they were well in excess of average monthly shipments nationally, West Virginia, and Cabell County.[1133]

44. For example, Custom Script Pharmacy, discussed above, is located in Barboursville in Cabell County. Barboursville had a 2010 population of 3,964.[1134] In the four-year period McKesson serviced Custom Script (2010 to 2013), it shipped to Custom Script 441,000 million doses of oxycodone and hydrocodone (based on ARCOS)—over 111 doses for every man, woman,

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[1128] *Id.*

[1129] *Id.*

[1130] FOF, ¶ 246.

[1131] FOF, ¶ 247.

[1132] P-44711_00027 (McCann 1006).

[1133] P-43225_00013, P-44711_00044.

[1134] FOF, ¶ 342.

and child. The four-year total masks the fact that Custom Script's orders from McKesson precipitously declined in 2012 and 2013.[1135] In 2011 alone, Custom Script purchased approximately 159,720 dosage units of oxycodone from McKesson, a monthly average of over 13,000 pills, and from 2006 to 2014, McKesson's average dosage units of oxycontin shipped to its Cabell and Huntington pharmacies was 4,467.[1136] For 2011, the average monthly dosage units of oxycontin shipped to Custom Scripts was over two times its average for all West Virginia pharmacies.[1137]

45. McKesson's Rite Aid sales in Cabell Huntington were also excessive when compared to its average sales in the county and state.[1138] The Rite Aid sales are even more problematic when one considers that during this time Rite Aid was also self-distributing opioids to its stores. From 2006 to 2014, McKesson shipped a total of 3,239,480 oxycodone and hydrocodone pills to the four Rite Aid pharmacies it serviced.[1139] Those totals were in addition to the 5,545,020 dosage units Rite Aid distributed to itself for those pharmacies resulting in 8,784,500 dosage units to these four stores.[1140]

46. Similarly, the vast volume of opioids ABDC and Cardinal supplied to certain pharmacies in Huntington and Cabell County and surrounding areas should have put them on notice that they were not supplying a legitimate market for the drugs.

[1135] *See* 44747_008.

[1136] FOF, ¶ 347; *See* 43225_0013.

[1137] *See* 44747_008.

[1138] FOF, ¶ 340.

[1139] FOF, ¶ 339.

[1140] *Id.*

47. For instance, Drug Emporium #1, discussed above, is located in Barboursville in Cabell County. Barboursville had a 2010 population of 3,964.[1141] ABDC shipped Drug Emporium #1 over 3.9 million doses of oxycodone and hydrocodone from 2006 through 2014 (based on ARCOS)—about 1,000 doses for every man, woman, and child.[1142] Huntington had a census population of 49,138 in 2010.[1143] From January 2006 through February 2012, ABDC shipped SafeScript 3,888,340 doses of oxycodone and hydrocodone, or nearly 80 doses per person.[1144]

48. Between January 2006 and December 2014, Cardinal sold and shipped 2,013,500 dosage units of oxycodone to the Medicine Shoppe in Cabell-Huntington – about 41 doses for every man, woman, and child in the city – from a single pharmacy.[1145] These totals are almost three times Cardinal's national and West Virginia averages and more than double its Cabell and Huntington average, representing over 150,000 oxycodone dosage units per year that Cardinal shipped into Cabell and Huntington.[1146]

49. The vast volume of opioids Defendants supplied to pharmacies in Huntington and Cabell County should have put Defendants on notice that they were not supplying a legitimate market for the drugs. Yet, though Mr. Rannazzisi testified – and common sense dictates – that distributors should consider the volume of opioids they sell to a customer or area relative to its

[1141] ECF No. 1433-7.

[1142] *See* 44711_00048 & ECF No. 1433-7 at p. 28.

[1143] ECF No. 1433-7.

[1144] P-44711_00044, P-43225_00001-6 & ECF No. 1433-7 at p. 28.

[1145] P-43225_00007.

[1146] FOF, ¶ 319; *see also* ¶¶ 535.

population, Defendants neither weighed these factors, nor even totaled their shipments of opioids into a jurisdiction, in assessing whether orders were suspicious or diversion might be occurring.[1147]

50. These figures actually undercount the volume of opioids that reached Huntington and Cabell County. As detailed by James Rafalski, an additional wave of opioids was making their way into West Virginia from Florida and other states via a route often referred to as the "Oxy Express" or "Blue Highway."[1148] Defendants' own documents acknowledge this migration.[1149] Furthermore, Defendants' excessive shipments to pharmacies in nearby counties, with populations a fraction of Cabell County also fueled the opioid crisis.[1150]

51. The Court concludes that Defendants knew or should have known of the significant effects resulting from their conduct. The addictive nature of opioid products and the history of their regulation allows the Court to conclude that Defendants had constructive knowledge that distribution of excessive quantities of opioids and failing to guard against diversion would lead to the opioid epidemic harms found above.[1151] Furthermore, based on the findings above, the Court

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[1147] 6/8 Trial Tr. (Rannazzisi) at 186 ("what we asked them to do is look at your suspicious – your pharmacy population, your customer population, identify anomalies within that population, ordering patterns, and then do your due diligence and see why those anomalies exist"); 5/17 Trial Tr. (Mays) at 203, 205 (between 2007 and 2014 the diversion control program did not rely on populations); Prevoznik, 5/17/19 Depo at 974 (DEA had said that knowledge of a geographic area's problem with controlled substance abuse is a factor that should be taken into account by registrants); *see also* 5/26/21 Trial Tr. (Rafalski) at 112 (orders the Defendants knew or should have known were suspicious were likely to be diverted into the illicit market).

[1148] 5/27 Trial Tr. (Rafalski) at 151-152 ("people that would get on airplanes in Huntington and fly to Florida to go to the pain clinics to get pills and then come back"; "Allegiant flight that was – they called it the Pill Express").

[1149] *See, e.g.,* FOF, ¶¶ 170, 367, 437, 438.

[1150] FOF, ¶¶ 334-337; 402-41.

[1151] FOF, ¶¶ 216, 444, 585, 592; FOF, Part III(B); *see also* COL, *infra,* Part ¶ V(B)(2).

concludes that there is ample evidence Defendants had actual knowledge of the effects of their conduct.[1152]

52. Defendants contend that the Plaintiffs have failed to provide evidence as to the "right" amount of prescription opioids that they should have shipped to customers in Cabell and Huntington. But the "right amount" is irrelevant when the amount actually shipped was so clearly excessive in proportion to the local population. The "right amount" is also irrelevant when Defendants had actual knowledge that the enormous quantities of opioids they were shipping into Cabell and Huntington were being supplemented with *more* opioids that had been diverted from surrounding counties in West Virginia and Florida. Whatever the "right amount" of opioids for Cabell and Huntington was, the quantities that Defendants shipped far exceeded it, and were unreasonable.

B. The Deficiencies in Defendants' Diversion Control Programs Establishes Unreasonable Conduct.

53. As discussed in detail above, key deficiencies marred each of Defendants' diversion control programs. And each diversion control program was carried out nationally, through centralized compliance staff. The Court concludes that the deficiencies in the creation, operation, and implementation of programs for detecting "suspicious orders" constituted unreasonable conduct.

54. All three Defendants' programs for detecting "suspicious orders" of prescription opioids were not designed to, and could not, detect a significant percentage of orders that were unusual in volume, pattern, or frequency to be indicative of diversion.[1153] Defendants each depended on monthly, volume-based thresholds for pharmacy customers as triggers for identifying

[1152] *See, e.g.,* FOF, Part II.A(2).

[1153] FOF, ¶¶ 128, 384 (ABDC); (Cardinal); 290-342 (McKesson)

potentially suspicious orders.[1154] And, by the time Defendants put these thresholds in place, opioid sales and, thus, customer purchasing baselines had already been inflated by nearly a decade of diversion and excessive sales. Therefore, they were set too high, and offered no meaningful brake on suspicious orders.

55. Each of the three Defendants also failed to perform due diligence on opioid orders they knew were suspicious to determine if diversion was likely, shipped orders of prescription opioids they knew were suspicious without first ascertaining that those orders were not likely to be diverted, and continued shipping opioids to pharmacies that they knew showed indicia of diversion.[1155]

56. Each of the Defendants failed to properly implement the suspicious order monitoring (SOMs) program that they did have.[1156] All three Defendants knew that their SOMs programs were inadequate and knew the devastating effects of the failure to maintain controls against diversion but failed to make changes to address the inadequacies.[1157]

57. Mr. Rafalski testified that Defendants' systemic failures to maintain effective controls were a substantial factor in the diversion of prescription opioids into Cabell-Huntington.[1158] He further testified that the orders Defendants knew or should have known were suspicious were likely to be diverted into Cabell-Huntington.

[1154] FOF, ¶¶ 141-158 (ABDC); 203, 220 (Cardinal); 257-313 (McKesson).

[1155] FOF, ¶¶ 140-158 (ABDC); 223-241 (Cardinal); 267, 280, 292, 307-338, 341, 343, (McKesson).

[1156] FOF, ¶¶ 105-126 (ABDC); 169-199 (Cardinal); 290-342 (McKesson).

[1157] FOF, ¶¶ 159-169 (ABDC); 192-222**,** 241 (Cardinal); 366-368 (McKesson).

[1158] FOF, ¶ 404.

58. The Court concludes that the deficiencies in all three Defendants' diversion control programs establishes unreasonable conduct for the purposes of Plaintiffs' public nuisance claim.

C. Defendants' Conduct was Unreasonable Because it Violated the CSA and the WVCSA.

59. Finally, the Court concludes that each of the Defendants violated the CSA and the WVCSA. This conclusion provides a final basis for determining that all three Defendants' conduct was unreasonable.

60. The CSA requires distributors like Defendants to design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); to report to the DEA suspicious orders when discovered (the "reporting duty"); and to decline to ship an order identified as suspicious unless and until, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty").[1159] The CSA defines suspicious orders to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[1160]

61. The WVCSA has corresponding duties. The West Virginia Controlled Substances Act ("WVCSA") is intended to be consistent with the federal CSA to the fullest extent practicable.[1161] The WVCSA, adopted in 1971, is derived from the Uniform Controlled Substances

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[1159] *See* 21 C.F.R. § 1301.74; *In re Nat'l Prescription Opiate Litig*., 1:17-md-02804-DAP, 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206, 212-213 (D.C. Cir. 2017); *see also Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007).

[1160] 21 C.F.R. § 1301.74(b).

[1161] *See* W.Va. Code § 60A–6–603 [1971] (the UCSA "shall be so applied and construed as to effectuate its general purpose to make uniform the law with respect to the subject of this [Act] among those states which enact it."). The West Virginia Board of Pharmacy has adopted, by

Act of 1970 ("UCSA").[1162] The UCSA, in turn, is similar to its federal counterpart, the CSA, and "was drafted to achieve uniformity between the laws of the several States and those of the Federal government.[1163]

62. The WVCSA provides that one of the qualifications for controlled substances licensure is that an applicant must operate "in compliance with all federal legal requirements applicable to wholesale drug distribution."[1164] Under the WVCSA, an applicant for a license to manufacture or distribute controlled substances is required to demonstrate that it provides "effective controls and procedures to guard against theft and diversion of controlled substances."[1165]

63. The Defendants contest the existence of the no-shipping duty, which does not expressly appear in the regulations.[1166] As the MDL Court explained, this last duty arises directly from the requirement to maintain effective controls against diversion set forth in 21 C.F.R. § 1301.71(a):

> [G]iven the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.[1167]

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reference, the requirements of the federal regulations, 21 CFR Parts 1300-1321, and 21 U.S.C. 801. W. Va. C.S.R. § 15-2-2, superseded by W. Va. C.S.R. § 15-2-3 (Apr. 1, 2020).

[1162] *State v. Young,* 185 W. Va. 327, 335, 406 S.E.2d 758, 766 (1991).

[1163] *Id.* Uniform Controlled Substances Act of 1970 prefatory note, vol. 9, part II, *U.L.A.* 2 (1988).

[1164] W. Va. Code § 60A-8-7(c)(1)(I).

[1165] W. Va. C.S.R. § 15-2-4.2.1, superseded by W. Va. C.S.R. § 15-2-5.1.1 (Apr. 1, 2020).

[1166] The Defendants also contend that the DEA historically approved SOMs which permitted the shipping of suspicious orders. These arguments are factually inaccurate. FOF, ¶¶ 139.

[1167] Opinion and Order Regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act, Dkt # 2483 at pp. 18-19.

63. On September 30, 2020, Judge Breyer, the federal district judge presiding over the case remanded from the MDL to the Northern District of California, adopted Judge Polster's conclusion on this point.[1168] More recently, Judge White, the federal district judge presiding over the case remanded from the MDL to the Eastern District of Oklahoma, adopted Judge Polster's conclusion that "there is not only a duty to report suspicious orders once detected, but also a duty to either not fulfill those orders or to investigate them to determine that they are not likely to be diverted to illegal channels.[1169] This Court joins these jurists and finds that the CSA (and the WVCSA) and their implementing regulations impose the no-shipping duty on Defendants. There can be no effective controls against diversion if a registrant is permitted to ship opioid orders it knows or should know the indicia of likely diversion.

64. The evidence presented at trial establishes that ABDC, Cardinal, and McKesson clearly violated the CSA and WVCSA. The volume of opioids shipped by the Defendants,[1170] the lack of controls to identify and stop suspicious orders,[1171] and their intentional disregard of what

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[1168] *See City and County of San Francisco v. Purdue Pharma L.P.*, No. 3:18-CV-07591-CRB, 2020 WL 5816488, at *4 (N.D. Cal. Sept. 30, 2020). Significantly, Judge Breyer held that the rulings of the MDL court were not binding on him but were "highly persuasive authority to the extent that these decisions are consistent with California and Ninth Circuit authority." 2020 WL 5816488, at *2. He specifically found Judge Polster's ruling with respect to the duties of distributors under the CSA to be "persuasive." *Id.*

[1169] *See The Cherokee Nation v. McKesson, et al*, No. CIV-18-056-RAW, Doc. # 288 at 9-10 (E.D. OK March 29, 2021).

[1170] See FOF, ¶¶ 174-187 (ABDC); FOF ¶¶ 189, 246-254 (Cardinal); FOF, ¶¶ 255, 338-360 (McKesson).

[1171] Defendants' programs for detecting "suspicious orders" of prescription opioids were not designed to, and could not, detect a significant percentage of orders that were sufficiently unusual in volume, pattern, or frequency to be indicative of diversion; Defendants failed to perform due diligence on opioid orders it knew were suspicious to determine if diversion was likely, shipped orders of prescription opioids it knew were suspicious without first ascertaining that those orders were not likely to be diverted, and continued shipping opioids to pharmacies that it knew showed

few procedures they had to protect the public[1172] each clearly establish statutory and regulatory violations. These violations of the CSA, WVCSA, and their relevant regulations are sufficient to allow the Court to conclude that Defendants acted unreasonably.

65. These violations of the law are sufficient to allow the Court to conclude that Defendants acted unreasonably. Defendants, however, Defendants argue that violations of the federal CSA or WVSCA cannot provide the basis for Plaintiffs' public nuisance claims as neither contain private rights of action. The Court rejects this argument.

66. Conduct that is unlawful is a basis for finding that an interference with a public right is unreasonable, and thus that a defendant may be found liable for creating or maintaining a nuisance.[1173] Public nuisance liability may also be based on unlawful conduct, regardless of *mens*

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indicia of diversion; and failed to implement their SOMs programs that were in place); *see* FOF, ¶¶ 131-158; 171-187 (ABDC); FOF, ¶¶ 167-231 (Cardinal); FOF, ¶¶ 266-365 (McKesson).

[1172] FOF, ¶¶ 164-166 (In its June 22, 2007 Settlement Agreement with the DEA, the covered conduct included ABDC's alleged failure to maintain adequate controls against diversion at the Orlando facility and all other facilities controlled by ABDC, and the alleged failure to detect and report suspicious orders as required by 21, C.F.R., 1301.74(b)); FOF, ¶¶ 200, 210 (In its September 2008 Settlement Agreement with the DEA, in which Cardinal paid a $34 million civil penalty, the covered conduct included Cardinal's alleged failure to maintain effective controls against diversion, on or prior to September 30, 2008, at all distribution facilities, including the Wheeling, WV distribution center servicing Cabell County and Huntington, WV); FOF, ¶¶261-264, 274, 312, 320-321, 342, 356, 361, 363. (In January 2017, McKesson entered into a $150 million settlement agreement with DEA for violations of the CSA associated with virtually all of its distribution centers, including the Washington Courthouse, OH distribution center that shipped opioids to Cabell County. McKesson agreed to a suspension of its license to distribute controlled substances from that distribution center (and others) for two years. As part of the 2017 settlement agreement, McKesson accepted responsibility for not identifying and reporting suspicious orders as required by the CSA and its previous settlement agreement in 2008 with DEA. McKesson has admitted that the systematic failure to report thousands of suspicious orders was "at the core" of the $150 million fine.)

[1173] *See, e.g., Duff*, 421 S.E.2d at 262 (reasonableness of conduct determines whether conduct constitutes a nuisance); *West v. National Mines Corp*., 168 W.Va. 578, 585-586, 285 S.E.2d 670, 676 (W. Va. 1981), *reh'g on appeal*, 336 S.E.2d 190 (W. Va. 1985) (activity must be reasonable to avoid liability for nuisance).

rea.[1174] Indeed, such conduct is considered an "absolute" nuisance or a "nuisance per se."[1175] That the unlawfulness of Defendants' conduct is relevant to whether that conduct constitutes or has created an unreasonable interference with a public right does not mean that Plaintiffs are seeking to enforce the CSA.

67. Indeed, it would make no sense for the Restatement to prescribe that a nuisance action may be predicated on the unlawfulness of the defendant's conduct if the only plaintiffs that could seek relief from the nuisance were those otherwise entitled to enforce the underlying statute. Nuisance actions are not so limited. Rather, as the Restatement makes clear, a public official or public agency representing a political subdivision may always bring an action to abate a nuisance.[1176] Indeed, West Virginia specifically empowers Plaintiffs to sue to abate a nuisance.[1177] This right to seek abatement is not limited based on the particular means of demonstrating that the interference with a public right is unreasonable. The additional element urged by Defendants, that the plaintiff must also have the right to enforce the statute that rendered the defendant's conduct unreasonable by virtue of its unlawfulness, appears nowhere in the Restatement or in West Virginia law. It has simply been manufactured by Defendants.

[1174] *See, e.g.,* Second Restatement § 821B(2)(ii) (noting that circumstances "that may sustain a holding that an interference with a public right is unreasonable[,]" include "whether the conduct is proscribed by a statute, ordinance, or administrative regulation");[1174] *West*, 285 S.E.2d at 676 (nuisance may arise from acts that are unlawful); *Morrisey,* 2014 WL 12814021, at *9 ("unreasonable interference" includes, *inter alia,* conduct that is contrary to a statute, ordinance, or regulation). West Virginia courts have rejected the argument that conduct *must* be unlawful in order to constitute a nuisance. *Lemongello*, 2003 WL 21488208 at *2.

[1175] Doc. 1248 at 8 ("[A]n act involving culpable and unlawful conduct causing unintentional harm" constitutes an "absolute nuisance," which is generally synonymous with a nuisance *per se*. *See* 66 C.J.S. Nuisances § 3.").

[1176] RESTATEMENT § 821C; *see also id.* at cmt. j.

[1177] *See* W.VA. CODE § 7-1-3kk; W.VA. CONST. art. 6, sec. 39a; W.VA. CODE § 8-12-2(8), (9-11).

68. Defendants rely on a single case involving indirect enforcement of statutes that do not provide for a private right of action, but that case is not on point and does not support their argument.[1178] Plaintiffs are not suing Defendants, directly or indirectly, for violating the CSA. They are suing Defendants for having created a public nuisance. While the illegality of Defendants' conduct is a factor in whether they can be liable for that nuisance, it is the nuisance itself, and not the CSA violation, that gives rise to Plaintiffs' claims. Plaintiffs are no more enforcing the CSA than a RICO plaintiff is enforcing the underlying criminal statutes that constitute RICO predicate acts.

* * * *

69. Based on all of the foregoing, the Court concludes that Plaintiffs have proven the interference with public rights by each of the Defendants in this case was unreasonable. Indeed, all three of the criteria of Section 821B(2) of the Second Restatement are met here. Plaintiffs have established (i) a significant interference with the public health, the public safety, the public peace,

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[1178] *See* ABDC Br. at 39 (*citing Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 118 (2011)). *Astra* involved the Public Health Services Act, which created price ceilings for drugs sold to certain health-care facilities, but provided no private right of action for those facilities to enforce the ceilings. *Id.* at 113. Drug manufacturers were, however, required, to sign a price "agreement" with the Secretary of Health and Human Services; the "agreement" included no negotiable terms and simply recited and recognized the manufacturers' responsibilities under the Act, including the price ceilings. *Id.* The Supreme Court in *Astra* rejected the health-care facilities' claim that they were third-party beneficiaries of the "agreements" and could sue for breach of contract to enforce those agreements. *Id.* at 113-14. The contractual claim rejected in *Astra* is wholly distinct from Plaintiffs' claims here. The Court in Astra refused to grant the plaintiffs third-party beneficiary status because doing so would have conflicted with a statutory scheme that gave enforcement power exclusively to the federal government and not to private parties. *Id.* at 121. This case is a public nuisance claim brought by governmental entities and neither federal nor state law preempts these claims. *See In re Nat'l Prescription Opiate Litig.,* 440 F.Supp.3d 773, 808 (N.D. Ohio 2020) (rejecting the Distributor Defendants' contention that "they are not subject to nuisance liability because their business activities are authorized and extensively regulated by state and federal law"); Dkt. 1285 at 7 (finding Defendants' state-law field preemption argument unavailing). The other cases cited by ABDC on this issue stand only for the anodyne proposition, not in dispute here, that private rights of action under federal statutes must be created by Congress.

the public comfort, or the public convenience, (ii) violations of statutes and regulations, and (iii), conduct that has produced a long-lasting effect that Defendants knew or should have known had a significant effect upon the public right.[1179]

V. The Defendants' Conduct Caused the Opioid Epidemic and the Resulting Public Nuisance in Cabell and Huntington.

70. West Virginia law requires a plaintiff to establish the element of causation in order to recover. Causation requires proof of two elements: (1) that the harm was the result of defendants' culpable conduct (cause in fact) and (2) the culpable conduct constitutes legal (or proximate) cause of the loss.[1180]

71. Ultimately, the determination of causation is a question of fact.[1181] In a bench trial, the Court is the finder of fact. Here, the Court concludes that the Plaintiffs have established that Defendants' unreasonable conduct was a cause in fact and a legal or proximate cause of the opioid epidemic harms in Plaintiffs' communities.

A. Defendants were a Cause in Fact of the Opioid Epidemic in Cabell County and the City of Huntington.

72. With respect to the first prong of the causation test, the factual findings above make it clear that Defendants were a contributing cause (indeed a substantial contributing cause) to the creation of an opioid epidemic in Cabell County and the City of Huntington. The Court's factual findings now lead to the legal conclusion that Defendants were "a cause" or a "contributing cause"

[1179] Second Restatement § 821B(2).

[1180] *Calvert v. Scharf*, 217 W. Va. 684, 690, 619 S.E.2d 197, 203 (2005) (plaintiff is required to prove that "negligence resulted in and was the proximate cause of loss to the plaintiff" (citations and internal quotations omitted)).

[1181] *See Qura v. D.R. McClain & Son*, 97 F.3d 1448 (4th Cir. 1996); *see also Aikens v. Debow*, 208 W.Va. 486, 490, 541 S.E.2d 576, 580 (W.Va. 2001) (same).

of the opioid epidemic and its resulting harms, and as such, were a cause in fact of the opioid epidemic.[1182]

73. With respect to the causation in fact requirement, all that a plaintiff is required to show proximate cause is that the action of a tortfeasor "contributes in any degree to the injury."[1183] The Plaintiffs' "burden of proof is to show that a [defendant's] breach of a particular duty was *a* proximate cause of the plaintiff's injury, *not the sole* proximate cause."[1184]

74. Under established causation principles, "[i]f a particular act might be expected to cause a particular result and, if that result has in fact followed, the conclusion may be justified that the causal relation exists."[1185] This is especially so where, as here, a plaintiff shows a statutory or regulatory violation.[1186] Put differently, it is sufficient for a plaintiff to present "evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct."[1187]

[1182] *Perry v. Melton*, 171 W. Va. 397, 400, 299 S.E.2d 8, 11 (1982); *Everly v. Columbia Gas,* 171 W. Va. 534, 536, 301 S.E.2d 165, 167 (1982).

[1183] *Wehner v. Weinstein*, 191 W. Va. 149, 155, 444 S.E.2d 27, 33 (1994); *see also Perry*, 171 W. Va. at 400 ("negligence must be a proximate or *contributing cause* before liability is established") (emphasis added)).

[1184] *Stephens v. Rakes*, 235 W. Va. 555, 565, 775 S.E.2d 107, 117 (2015) (emphasis added); *Everly v. Columbia Gas of W. Virginia, Inc*., 171 W. Va. at 536, 301 S.E.2d at 167 (1982) (same).

[1185] Second Restatement, § 433B, comment b (1965); *see also Huskey v. Ethicon*, Civil Action No. 2:12-cv-05201, 2015 WL 4944339, at *6 (S.D.W. Va. Aug. 19, 2015), aff'd, 848 F.3d 151 (4th Cir. 2017) (same).

[1186] *See*, *e.g.*, *Gillingham v. Stephenson*, 209 W. Va. 741, 749, 551 S.E.2d 663, 671 (2001) ("'The violation of the statute is rightly considered the proximate cause of any injury which is a natural, probable, and anticipated consequence of the nonobservance.'") (quoting *Noman v. Virginia Pocahontas Coal Co.*, Syl. pt. 2, 68 W. Va. 405, 69 S.E. 857 (1910)).

[1187] *BCS Servs., Inc. v. Heartwood 88*, 637 F.3d 750, 758 (7th Cir. 2011) (J. Posner). This is particularly true where, as here, a plaintiff shows a statutory violation: "The violation of the statute is rightly considered the proximate cause of any injury which is a natural, probable, and anticipated consequence of the nonobservance." *Gillingham v. Stephenson*, 209 W. Va. at 748–49, 551 S.E.2d

75. First, Defendants' failure to maintain adequate and effective controls against diversion was a substantial contributing cause of the diversion of prescription opioid pills shipped to Cabell County, the City of Huntington, and the surrounding region.[1188] Moreover, here the expected result of the failure to maintain adequate and effective controls against diversion is the exact result that occurred in Plaintiffs' communities,[1189] which independently justifies the Court's conclusion "that the causal relation exists."[1190] Furthermore, Defendants' failure to maintain effective controls outside of Cabell and Huntington contributed to diversion in Cabell and Huntington and the resulting harms.[1191]

76. Second, the oversupply of opioids substantially contributed to the opioid epidemic and the harms resulting from it. This conclusion was largely undisputed at trial. Plaintiffs' experts,[1192] DEA witnesses,[1193] and Defendants' officers[1194] all provided testimony supporting this conclusion. Indeed, the testimony from Defendants' substance use disorder care systems expert that "oversupply of prescription opioids is not *the* causal factor of the opioid epidemic, but

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at 671 (2001) (quotation omitted). Judge Polster has found similarly in denying summary judgment on proximate causation. *See* Opinion and Order regarding Defendants' Summary Judgment Motions on Causation, *In re: Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804, Dkt. 2561, 2019 WL 4178617 at 2-3 (N.D. Ohio Sept. 3, 2019).

[1188] FOF, ¶ 410.

[1189] FOF, ¶¶ 411-419.

[1190] Second Restatement, § 433B, comment b (1965); *Huskey v. Ethicon*, 2015 WL 4944339, at *6.

[1191] FOF, ¶¶ 425-438.

[1192] FOF, ¶¶ 442-444.

[1193] FOF, ¶ 440.

[1194] FOF, ¶¶ 445.

is only *a* causal factor"[1195] easily fits withing the bounds of West Virginia law on causation.[1196] Similarly, the evidence is overwhelming that diversion was a substantial factor in causing the community harms resulting from the opioid epidemic – overdose deaths, opioid use disorder, heroin/fentanyl use, infectious diseases, and disruption to children and families.[1197]

77. Third, while Defendants contend that they believed that they were shipping to legitimate pharmacies to fill legitimate prescriptions, the evidence at trial established that Defendants' systematic failures to maintain adequate and effective controls against diversion substantially contributed to shipments of tens of millions of opioid pills to Cabell County, the City of Huntington, and the surrounding region that were not prescribed in accordance with the standard of care.[1198] Instead, it is likely that these shipments were diverted to illicit, non-medical use, contributing substantially to the resulting opioid epidemic harms in Cabell and Huntington.[1199]

78. In making this argument, the Defendants ignore West Virginia law which recognizes the likelihood that certain harms will have more than one cause-in-fact.[1200] In this setting, a plaintiff's burden is to show that a particular defendant's conduct "was a proximate cause

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[1195] FOF, ¶ 446.

[1196] *Stephens v. Rakes*, 235 W. Va. at 565, 775 S.E.2d at 117 (unnecessary for plaintiff to prove defendant's conduct was the sole cause).

[1197] FOF, ¶¶ 1-79.

[1198] FOF, ¶ 524.

[1199] *Id.*

[1200] *See Wehner*, 191 W. Va. at 155, 444 S.E.2d at 33 (recognizing doctrine of "concurrent negligence").

of the plaintiff's injury, not the sole proximate cause,"[1201] and the plaintiff satisfies this burden by showing that the defendant's conduct "contributes in any degree to the injury."[1202]

79. Plaintiffs satisfied this burden. As set forth above, the evidence shows that Defendants' diversion control failures resulted in them shipping tens of millions of opioid dosage units to and near Cabell and Huntington that could not have been prescribed for medically legitimate purposes, even under the then-prevailing standard of care for pain treatment.

80. The large volume of pills sent to some of Defendants' pharmacy customers without conducting due diligence was used to fill prescriptions written by physicians who were disciplined for improper prescribing practices. [1203] One of these physicians represented between 50% and 70% of the prescriptions filled by the individual pharmacies served by the Defendants.[1204] Two physicians whose prescribing led to licensure revocation were responsible for 24 million-plus opioid dosage units they prescribed in Cabell County before losing their licenses.[1205]

81. The Court can also conclude that the extreme quantities of pills shipped to customers in Cabell County and surrounding areas led to diversion and the resulting harms. These extreme quantities of opioid pills well over Defendants' county, state, and national shipment averages are unexplained by any due diligence,[1206] and indeed, the quantities alone show "no conceivable medical need."[1207] Fact and expert testimony from Plaintiffs' and Defendants'

[1201] *Stephens*, 235 W. Va. at 565, 775 S.E.2d at 117 (internal quotation marks and citations omitted).

[1202] *Wehner*, 191 W. Va. at 155, 444 S.E.2d at 33.

[1203] FOF, ¶¶ 345-346, 526-531.

[1204] FOF, ¶¶ 510, 513.

[1205] FOF, ¶ 520.

[1206] FOF, ¶¶ 441,457, 472, 473.

[1207] FOF, ¶ 574.

witnesses supports the conclusion that oversupply leads to diversion and the resulting harms from the opioid epidemic.[1208]

82. The Court concludes that Defendants' failure to stop shipments to these pharmacies and physicians engaging in unscrupulous conduct is a substantial factor in the diversion of opioids in Cabell and Huntington and likely led to the creation of "large pockets of addicts" and "cause[d] enormous harm."[1209]

83. Finally, even if the Defendants are correct and the immense volume of opioids they shipped to Cabell and Huntington was due solely or primarily to increased good faith prescribing, Defendants still would be liable because their diversion control failures still would be a concurrent cause of the opioid oversupply and public nuisance harms.

84. Defendants have a legal duty not to ship orders they have or should have identified as suspicious unless the order is cleared.[1210] As set forth above, Plaintiffs' diversion control investigations and SOMS expert, Mr. Rafalski, determined using Defendants' own metrics and those used by other distributors and/or approved by the D.C. Circuit in *Masters* that Defendants shipped orders totaling at least 31,153,000 dosage units of oxycodone and hydrocodone into Cabell and Huntington that should have been flagged and blocked pending or absent investigation.[1211] He

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[1208] FOF ¶¶ 441, 446, 457, 591-601.

[1209] FOF, ¶ 521.

[1210] *See Masters Pharm., Inc.*, 861 F.3d at 212-13 ("Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)."); *id.* at 221-22 ("As noted above, the Shipping requirement mandates that pharmaceutical companies exercise 'due diligence' before shipping any suspicious order."); *see also In re Nat'l Prescr. Opiate Litig.*, 2019 WL 3917575 at *9 ("In sum, the Court concludes that the CSA statutory and regulatory duties to maintain effective controls against diversion includes a duty not to ship suspicious orders.").

[1211] FOF, ¶ 369.

further found that there was insufficient evidence in Defendants' customer files to dispel the suspicions raised by these orders and permit their shipment,[1212] and Defendants have not shown otherwise.

85. Since Defendants were under a legal duty not to ship these orders absent due diligence, these shipments are a concurrent and actionable cause of the diversion, oversupply, and nuisance harms in Cabell and Huntington. This is precisely what the court held in *City and County of San Francisco* where the same distributor defendants argued for dismissal on the grounds that their conduct could not be the legal cause of opioid epidemic harms because "Manufacturers' marketing campaign 'created the new standard of care' causing an increase in prescriptions that Distributors had 'no ability (and no duty) to second-guess.'"[1213] The *San Francisco* Court rejected this argument, holding instead that distributors could be liable based on principles of concurrent liability: "the City has not alleged that Manufacturers' false marketing caused the Distributors' failure to maintain effective controls, nor vice versa. Rather, both parties' conduct allegedly caused the City's injuries."[1214] The same conclusion applies here under the well-established West Virginia law.[1215]

B. Defendants Were a Proximate Cause of the Opioid Epidemic Harms in Cabell County and the City of Huntington.

86. The Court concludes that each Defendant is a legal or proximate cause of the opioid epidemic harms in Cabell and Huntington. Under West Virginia law, a defendant's conduct that

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[1212] FOF, ¶ 369, 371.

[1213] *City and County of San Francisco,* 2020 WL 5816488 at *45.

[1214] *Id.* As such, what the undone due diligence would have shown is irrelevant. Since Defendants had a legal duty to stop flagged orders and only ship them if investigation cleared them, which they did not do, this failure caused the harms regardless of what any investigations *might have* shown because those investigations were not done, and the shipments therefore could not be made.

[1215] *See* COL, ¶ 76 (discussing a plaintiffs' burden when concurrent liability exists).

contributes to (*i.e.*, is a factual cause of) the plaintiff's harm also is deemed a legal or proximate cause if the harm that occurred was reasonably foreseeable to the defendant. The Supreme Court of Appeals recently summarized the standard for determining proximate cause:

> [Proximate cause] is that cause which in actual sequence, unbroken by any independent cause, produced the wrong complained of, without which the wrong would not have occurred. An intervening cause, however, may jump in, break that chain of causation, and so constitute the new, effective cause of the injury. We have held that an intervening cause, in order to relieve a person charged with negligence in connection with an injury, must be a negligent act, or omission, which constitutes a new effective cause and operates independently of any other act, making it and it only, the proximate cause of the injury. But not every intervening event wipes out another's preceding negligence. In fact, a tortfeasor whose negligence is a substantial factor in bringing about injuries is not relieved from liability by the intervening acts of third persons if those acts were reasonably foreseeable by the original tortfeasor at the time of his negligent conduct.[1216]

87. The fact that a third party's intervening acts were intentional or even criminal is not dispositive, as liability may be imposed if defendants' affirmative actions or omissions have unreasonably created or increased the risk of injury from the criminal activity of a third party.[1217] Thus, the inquiry where allegedly intervening criminal acts occur is whether the defendant's "wrongful acts co-operate with, augment, or accelerate those forces to the injury of another."[1218] A defendant bears the burden of proving that intervening acts are a superseding cause.[1219] The defendant must show that the intervening conduct "constitutes a new and effective cause and operates independently of any other act, making it and it only, the proximate cause of the

[1216] *Wal-Mart Stores E., L.P. v. Ankrom*, 244 W. Va. 437, 854 S.E.2d 257, 270 (2020) (citations and internal quotations omitted).

[1217] *Estate of Hough ex rel. Lemaster v. Estate of Hough ex rel. Berkely Cty. Sheriff*, 205 W. Va. 537, 545 (1999).

[1218] *In re Flood Litig.*, 216 W. Va. 534, 549, 607 S.E.2d 863, 878 (2004).

[1219] *Sydenstricker v. Mohan*, 217 W. Va. 552, 559, 618 S.E.2d 561, 568 (2005).

injury."[1220] Finally, "[t]he rule employed with respect to limitations on liability, whatever label is used, in public nuisance actions must be less restrictive than in individual tort actions.' As such, in public nuisance claims, 'where the welfare and safety of an entire community is at stake*, the cause need not be so proximate as in individual negligence cases*.'"[1221]

1. Defendants Cannot Prevail on Legal Causation by Using "Directness" Concepts Imported from Federal Statutes to Rewrite West Virginia's Long-Established and Recently Reaffirmed Foreseeability Standard.

88. Defendants argue that reasonable foreseeability *is not* the standard for legal causation in West Virginia. The Court concludes that this argument is simply incorrect.

89. First, the case Defendants rely on, *Aikens v. Debow*, reaffirms that foreseeability is the touchstone for legal causation.[1222] The "remoteness" language Defendants quote is from a passage describing *federal* law.[1223] Indeed, the Supreme Court of Appeals in *Aikens* went on to hold under West Virginia law that a plaintiff sustaining purely economic damages may recover in tort in circumstances showing that "the tortfeasor had a duty to the particular plaintiff and that *the injury complained of was clearly foreseeable to the tortfeasor*."[1224]

[1220] *Wehner,* 191 W. Va. at 155.

[1221] *Brooke County Commission v. Purdue Pharma L.P. et al*., No. 17-C-248 at 14 (W.Va. Cir. Ct. Dec. 28, 2018) (emphasis added)) (quoting *NAACP v. AcuSport, Inc.*, 271 F. Supp. 2d 435, 497 (E.D.N.Y. 2003)); *see also In re Nat'l Prescr. Opiate Litig.*, 2019 WL 2468267, at *32 (N.D. Ohio April 1, 2019) (Ruiz, M.J., Report and Recommendation) (same) (quoting *NAACP*), *adopted in relevant part*, 2019 WL 3737023, at *9-11 (N.D. Ohio June 13, 2019) (Polster, J.)).

[1222] 208 W. Va. 486, 492, 541 S.E.2d 576, 582 (2000).

[1223] *See Aikens*, 208 W. Va. at 492, 541 S.E.2d at 582 ("The Supreme Court reasoned that the doctrine of remoteness is a component of proximate cause, which in turn embraces the concept that 'the judicial remedy cannot encompass every conceivable harm that can be traced to alleged wrongdoing.'") (quoting *Associated Gen. Contractors of Calif., Inc. v. Calif. State Council of Carpenters*, 459 U.S. 519, 536 (1983) (antitrust case)).

[1224] *Id.* at 499, 541 S.E.2d at 589 (emphasis added).

90. Second, Defendants' reliance on other federal case law to try to rewrite West Virginia law is equally unavailing. Defendants argue that "[t]o avoid judgment on proximate causation grounds, Plaintiffs must have evidence of a ***'direct relation*** between the injury asserted and the injurious conduct alleged.'"[1225] This argument fails because the case relied upon, *Holmes, supra,* addresses federal, not West Virginia law.[1226] The Court in *San Francisco* recognized the difference. When faced with the federal RICO claims, the Court dismissed claims based on opioid marketing and promotion where "the City's harm extends well beyond the first step."[1227] It applied a different standard and refused to dismiss state law based public nuisance claims on proximate causation grounds where, "Manufacturers' alleged false promotion could foreseeably result in increased opioid addiction, abuse, and overdoses, *Distributors' alleged failure to maintain effective controls against diversion could foreseeably result in the same harms.*"[1228] A similar conclusion applies here – West Virginia's foreseeability standard governs.

91. Finally, Defendants' reliance on two decisions of this Court – *Employer Teamsters v. Bristol Myers Squibb Co.*,[1229] and *City of Charleston v. Joint Comm'n*,[1230] -- also fails.

92. In *Employer Teamsters*, the Court addressed implied warranty and unjust enrichment claims by a health insurer for economic losses caused by the defendant's deceptive marketing of a prescription drug taken by some of the plaintiffs' insureds.[1231] The Court applied

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[1225] Doc. 1469 at 48 (citing *Holmes v. Sec. Inv'r Prot. Corp.,* 503 U.S. 258, 268 and 271-72 (1992).

[1226] *See* 503 U.S. at 265-68 (addressing federal RICO causation standard).

[1227] *San Francisco v. Purdue Pharma,* 491 F. Supp. 3d 610 at 657 (N.D. Cal. 2020).

[1228] *Id.* at 683 (emphasis added).

[1229] 969 F. Supp. 2d 463 (S.D. W. Va. 2013).

[1230] 473 F. Supp. 3d 596 (S.D. W. Va. 2020).

[1231] *Id.* at 466.

the *Holmes* "direct relation" standard of legal causation, in dismissing these contract-based claims, but did so without addressing (or having occasion to address) the foreseeability standard of legal causation for non-contractual tort claims under West Virginia law.[1232]

93. In *City of Charleston*, the Court addressed negligence and unjust enrichment claims by the city against the Joint Commission on Accreditation of Health Care Organizations ("JCAH") for its conduct influencing the medical standard of care for pain treatment towards greater opioid prescribing.[1233] In dismissing the claims, the Court held that there was no special relationship or privity of contract between the parties to prevent application of the economic loss rule as a bar to claims for purely economic damages.[1234] After recognizing this ground for dismissal, the Court proceeded to discuss the separate question of duty and held that the city's claim involved harms from the opioid epidemic that were not foreseeable to the Joint Commission as a trade association.[1235]

94. Notably, *City of Charleston* distinguished the claim against JCAH from the claim against these Defendants citing the MDL Court's prior decision.[1236] The Court found that the JCAH as a trade association was differently situated from opioid manufacturers and distributors, which operate under diversion-control duties that make public health and safety harms like those at issue there and here foreseeable.[1237]

[1232] *Id.* at 475.

[1233] 473 F. Supp. 3d at 608.

[1234] *Id.* at 619.

[1235] *Id.* at 622.

[1236] *Id.* at 620 (*In re Nat'l Prescr. Opiate Litig.: County of Summit, Ohio v. Purdue Pharma L.P.*, No. 1:17-md-2804, 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018)).

[1237] *Id.* at 621 ("Unlike the manufacturer and distributor defendants in *Summit County*, defendants here had no control or responsibility over the manufacturing or distributing of opioids.").

95. Since *Employer Teamsters* addressed contract-based claims, not tort claims, and *City of Charleston* expressly distinguished claims against distributors with respect to duty and foreseeability, neither supports overturning well-established West Virginia law applying reasonable foreseeability as the standard for assessing legal causation. Indeed, the Supreme Court of Appeals recently, and subsequent to the decisions in both *Employer Teamsters* and *City of Charleston*, reaffirmed that "'a tortfeasor whose negligence is a substantial factor in bringing about injuries is not relieved from liability by the intervening acts of third persons if those acts were reasonably foreseeable by the original tortfeasor at the time of his negligent conduct.'"[1238]

96. The Court declines to extend these decisions and rejects Defendants' invitation to apply the *Holmes'* remoteness test in this case involving West Virginia public nuisance law.[1239]

2. Proximate Cause is Established in this Case as the Opioid Epidemic Harms Were Reasonably Foreseeable to Defendants.

97. The Court concludes that the opioid epidemic public health and safety harms afflicting Cabell County and the City of Huntington were reasonably foreseeable to, and foreseen by, Defendants when they engaged in the diversion control failure set forth above.

98. This foreseeability is demonstrated in the Controlled Substances Act itself, which sets forth Congress's finding that the "illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people."[1240] And, the Supreme Court also has

[1238] Syl Pt. 9, *Wal-Mart Stores East, L.P. v. Ankrom*, 244 W.Va. 437, 854 S.E.2d 257 (quoting *Anderson v. Moulder*, *supra*).

[1239] Even if it were a close question, the Court would decline to apply *Holmes* to a public nuisance claim implicating health and safety as proximate cause standards are not as strict in the context of a public nuisance case. *Brooke County Commission v. Purdue Pharma L.P. et al*., *supra* at 14.

[1240] 21 U.S.C. § 801(2).

recognized that, in enacting the CSA, "Congress was particularly concerned with the diversion of drugs from legitimate to illegitimate channels."[1241] In *Direct Sales Co. v. U.S.*, the Supreme Court recognized in addressing the CSA's predecessor statute, the Harrison Act, that "[t]he difference between sugar, cans, and other articles of normal trade, on the one hand, and narcotic drugs, machine guns and such restricted commodities, on the other, aris[es] from the latters' inherent capacity for harm and from the very fact that they are restricted."[1242]

99. Defendants' duty to maintain effective controls and procedures to guard against theft and diversion of controlled substances, arise out of this inherent capacity to cause public health and safety harms. This is precisely why other courts addressing public nuisance claims against opioid distributors and manufacturers based upon breaches of CSA duties have held that the foreseeability element of proximate causation is evident in the duty and breach themselves. As Judge Breyer explained in *City and County of San Francisco*, *supra*:

> The very existence of the duties to maintain effective controls supports the nation that opioid use is foreseeable. "A lack of reasonable care in the handling, distribution, and administration of controlled substances can foreseeably harm the individuals who take them. That's why they're 'controlled' in the first place—overuse or misuse can lead to addictions and long-term health problems.[1243]

[1241] *U.S. v. Moore*, 423 U.S. 122, 135 (1975) (citing H.R. Rep. No. 91-1444, p. 6; S. Rep. No. 91-613, pp. 4; 116 Cong. Rec. 996 (1970)); *see also Gonzalez v. Raich*, 545 U.S. 1, 12-13 (2005) ("Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels.") (citing *Moore*).

[1242] 319 U.S. 703, 711 (1943).

[1243] 491 F. Supp. 3d at 680 (quoting *Dent v. NFL*, 902 F.3d 1109, 1119 (9th Cir. 2018)); *see also In re Nat'l Prescr. Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4178617, at *4 (N.D. Ohio Sept. 3, 2019) ("Because Plaintiffs have presented evidence that shows they suffered the sort of injury that would be an expected consequence of the alleged wrongful conduct, Plaintiffs have done enough to withstand summary judgment on this issue.").

100. Whether the harms were self-evident or not, Plaintiffs also have produced substantial evidence showing that the opioid epidemic's public health and safety harms were reasonably foreseeable to and foreseen by Defendants.

101. First, as noted above, the Court has found that substantial evidence from the DEA, Plaintiffs' experts, and Defendants themselves demonstrates that Defendants' failures to maintain effective controls against diversion and the resulting oversupply would foreseeably result in the occurrence of diversion.[1244]

102. Second, the Court found that there likewise is widespread agreement among the DEA, Plaintiffs' experts, and Defendants that diversion and oversupply of prescription opioids made the public health and safety harms that are afflicting Cabell and Huntington foreseeable.[1245]

103. Finally, Defendants place great focus on the fact that some harms from the opioid epidemic result from illegal use of heroin and fentanyl. The emphasis on illegality is not echoed in West Virginia law:

> Petitioner essentially argues that criminal acts are *per se* intervening causes. . . . Once again, however, petitioner relies on a generality . . . with little regard for the exception [that] . . . a tortfeasor whose negligence is a substantial factor in bringing about injuries is not relieved from liability if the intervening acts were reasonably foreseeable.'"[1246]

Here, the Court has found that there is widespread agreement among Plaintiffs' and Defendants' expert witnesses on facts showing that the development of heroin and fentanyl addiction harms

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[1244] FOF, ¶¶ 564-572 (noting testimony of Rannazzisi (DEA), Courtwright (Plaintiffs' expert), Hartle (McKesson's Rule 30(b)(6) witness), Reardon (Cardinal), Hazewski (ABDC), and Gilligan (Defendants' expert)).

[1245] FOF, ¶¶ 573-77 (noting testimony of Rannazzisi, Courtwright, Waller (Plaintiffs' expert), Keyes (Plaintiffs' expert), and Hartle).

[1246] *Marcus v. Staubs*, 230 W. Va. 127, 139, 736 S.E.2d 360, 372 (2012) (quoting *Anderson v. Moulder*, 183 W. Va. 77, 394 S.E.2d 61 (1990)).

was another foreseeable consequence of the diversion and oversupply of prescription opioid pills into communities like Cabell and Huntington.[1247]

104. West Virginia state courts handling similar opioid litigation claims have rejected the arguments made by the Defendants.[1248] In the MDL, Judge Polster rejected Defendants' arguments concerning a too-attenuated causal chain, observing that "the relationship between Plaintiffs' injury and Defendants' alleged conduct . . . is not too remote to support a finding of proximate cause here."[1249] Most recently, as noted above the Northern District of California in *City and County of San Francisco* rejected similar causation arguments.[1250] The vast majority of courts addressing opioid litigation around the county are in accord.[1251]

[1247] FOF, ¶¶ 578-585 (noting testimony of Waller, Keyes, Alexander (Plaintiffs' expert), Hartle, Gilligan (Defendants' expert), and Murphy (Defendants' expert)).

[1248] In *SER Morrisey v. AmerisourceBergen Drug Corp.*, 2014 WL 12814021 (W.Va Boone Cty. Cir. Ct. Dec. 12, 2014) at 11-12, West Virginia brought claims against opioid distributors for nearly the exact conduct and harms alleged here. Analyzing West Virginia law, the court found that any alleged intervening acts were foreseeable to Defendants, and therefore insufficient to cut off the chain of liability as a matter of law. Similarly, in *Brooke County*, the West Virginia Circuit Court rejected distributor defendants proximate cause arguments, finding that: "Defendants' conduct was not too remote from the opioid epidemic—even considering that third party conduct may have also contributed to the opioid epidemic—and that the acts of third parties (even criminals) were foreseeable and did not create a new effective cause or operative independently." *See Brooke Cty. Comm'n v. Purdue Pharma, L.P.*, No. 17-C-248, p. 12 (W. Va. Marshall Cty. Cir. Ct. Dec. 28, 2018).

[1249] 1:17-md-02804, Dkt. 1203, at 9-10.

[1250] *City and County of San Francisco, et al. v. Purdue Pharma L.P., et al.,* 3:18-cv-07591, 2020 WL 5816488, at *69-80 (N. D. Cal. Sept. 30, 2020)

[1251] *See, e.g*, *Commonwealth v. Purdue Pharma, L.P.*, 2019 WL 6497887 (Mass. Super. Nov. 6, 2019); *City of Chicago v. Purdue Pharma, L.P.,* 211 F. Supp. 3d 1058 (N.D. Ill. 2016); *Grewal v. Purdue Pharma L.P.*, 2018 WL 4829660 (N.J.Super.Ch. Oct. 2, 2018); *Com. v. Endo Health Solutions Inc*., 2018 WL 3635765 (Ky. Cir. Ct. July 10, 2018); *State v. Purdue Pharma L.P*., 2019 WL 2331282 (Tenn. Cir. Ct. Feb. 22, 2019); *State v. Purdue Pharma L.P*., 2018 WL 4468439 (Alaska Super. July 12, 2018); *State, ex rel. Dewine v. Purdue Pharma L.P.,* 2018 WL 4080052 (Ohio Com.Pl. Aug. 22, 2018); *State v. Purdue Pharma Inc*., 2018 WL 4566129 (N.H. Super. Sep. 18, 2018).

105. The Court concludes that Defendants could reasonably foresee, and in fact foresaw, that their diversion control failures as found herein would result in the opioid epidemic public health and safety harms afflicting Cabell County and the City of Huntington, including the epidemic's evolution from one primarily of prescription opioid abuse to one intertwined with heroin and fentanyl abuse. As such, as foreseeability is the touchstone for determining proximate cause,[1252] the Court concludes that Defendants have failed to meet their burden of showing that intervening causes break the causal chain and relieve them from liability.[1253]

VI. Plaintiffs' Claims Are Not Barred by the Statute of Limitations

A. There is No Statute of Limitations for Claims Sounding in Equity.

106. In West Virginia, there is no statute of limitations for a claim sounding in equity.[1254] Plaintiffs are seeking equitable relief. This Court has previously rejected the Defendants' argument that the prospective remedy of abatement sought by Plaintiffs cannot include a monetary award to fund an abatement plan.[1255]

107. Defendants have conceded that "the statute of limitations does not bar the government from enjoining a continuing nuisance,"[1256] but they have failed to explain why this same theory does not apply to other equitable remedies. Plaintiffs are not seeking future damages

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[1252] *State ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, 2014 WL 12814021, at *2 (W.Va. Boone Cty. Cir.Ct. Dec. 12, 2014); *see also Wal-Mart Stores East, L.P. v. Ankrom*, 244 W. Va. 437, 854 S.E.2d at 270.

[1253] *Cf. Sydenstricker,* 217 W. Va. at 559, 618 S.E.2d at 568 (defendant bears the burden of proving that intervening acts break the causal chain).

[1254] *Dunn v. Rockwell,* Syl. pt. 6, 255 W.Va. 43, 689 S.E.2d 255 (2009). *Dunn* reemphasized decades of precedent and reaffirmed its prior holdings: "Our law is clear that there is no statute of limitation for claims seeking equitable relief." *Id.* at 266; *see also* n.9 (citing cases).

[1255] Doc. 1285 at 6.

[1256] Doc. 241 at 23.

or "reimbursement for public expenditures."[1257] As Defendants point out, Plaintiffs have "expressly abandoned any claim for past and future economic losses."[1258] Instead, Plaintiffs have made it clear that they are seeking abatement which is equitable in nature and provides a prospective remedy that allows plaintiffs to recover the costs of rectifying the nuisance.

108. Funding future treatment and education to eradicate the epidemic Defendants wrought is not a damage claim because such funding is not compensation for an injury to Plaintiffs; rather it is the cost that must be incurred to reverse the conditions causing an interference with the public's right to health and safety. Future damages, a legal remedy, seeks to compensate Plaintiffs for the cost of injuries that will continue into the future—such as, for example, lost tax revenue—whereas abatement, an equitable remedy, addresses the costs of actions to prevent or lessen such future harms, in this case actions that will reduce or eliminate the ongoing opioid crisis in Plaintiffs' communities. Abatement expenditures represent what would need to be spent, *whether by Plaintiffs or other entities*, to remediate the nuisance. The fact that there may be common elements between certain types of future damages and an abatement plan does not transform abatement into damages, any more than baseball becomes football when their seasons overlap in September.

109. This Court finds that based on the clear holding in *Dunn*, there is no statute of limitations for Plaintiffs' claims which seek equitable relief.

[1257] *Id.* at 24.

[1258] *Id.* at 1 (internal quotations omitted).

B. Even if Plaintiffs' Claim is Considered Legal, There is No Statute of Limitations for an Unabated Temporary Nuisance.

110. Under West Virginia law, the statute of limitations does not run on an unabated public nuisance.[1259]

111. In *Kermit* Lumber, the Court noted that nuisance cases in West Virginia were characterized as either permanent or temporary for the purposes of analyzing whether an action is time-barred.[1260] A permanent nuisance is a "type of nuisance where by one act a permanent injury is done being at once necessarily productive of all the damage which can ever result from it."[1261] By contrast, temporary nuisances involve "continuing or repeated injury."[1262] The statute of limitations for a permanent nuisance begins to run immediately, while, when the nuisance is classified as temporary, "suits may be maintained as damage goes on."[1263] In *Kermit Lumber*, the Supreme Court found that the public nuisance the DEP alleged was an unabated and temporary one for which the statute of limitations would not run unless and until abatement occurred.[1264] *Kermit Lumber* governs here and is dispositive.

112. The first step in the *Kermit Lumber* analysis is to determine whether the nuisance alleged is one that is temporary or permanent.[1265] In making this determination here, it is important to recognize that this is a governmental action seeking to abate a public nuisance. A "public

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[1259] *State ex rel. Smith v. Kermit Lumber & Pressure Treating Co.*, Syl. pt. 11, 200 W.Va. 221, 488 S.E.2d 901 (1997).

[1260] *Id.* at 922-24.

[1261] *Id.* at 922–23 (quoting 58 Am.Jur.2d Nuisances § 27 (1989)).

[1262] *Id.* at 923.

[1263] *Id*.

[1264] *Id.* at 925.

[1265] *Id.* at 923.

nuisance is by nature continuous or recurring."[1266] That is because "[a] public nuisance action usually seeks to have some harm which affects the public health and safety abated."[1267]

113. Defendants do not contend that the harms to the public health and safety here are either abated or can never be abated. Thus, the nature of the public nuisance here is indistinguishable from the unremediated hazardous waste in *Kermit Lumber*. Like hazardous waste, the impact of the opioid epidemic continues to spread.[1268] And like the hazardous waste in *Kermit Lumber,* the opioid epidemic can be remediated. The "ability to abate" test is recognized by the Supreme Court as a means to determine whether a nuisance is temporary or permanent.[1269]

114. The Court finds that the ability to abate test is met here, and the public nuisance is a temporary one.[1270]

115. With a public nuisance that is temporary (and thus abatable), the statute of limitations does not begin to run until the nuisance is abated. Thus, when "a public nuisance action is brought in order to remediate" harms to public health, public safety, and the environment, the statute of limitations does not begin to run, "until the harm or endangerment to the public health, safety and the environment is abated."[1271]

116. Ignoring *Kermit Lumber,* Defendants focus on their nuisance-causing conduct rather than the continued existence of the public health crisis that resulted from that conduct.[1272]

[1266] *Id.* at 925.

[1267] *Id.*

[1268] *See* FOF, Part I.

[1269] *Id.* at 923, n.26.

[1270] FOF, ¶ 614(g) ("The harms resulting from the opioid epidemic are capable of being abated").

[1271] *Kermit Lumber,* 488 S.E.2d at 925, at Syl. Pt. 11.

[1272] Doc. 241 at 18-21.

This analysis misses the mark when the action involves an unabated public nuisance, where *"whether a nuisance will be classified as continuing or permanent depends not on the offending party's interest in continuing the nuisance, but on the type of harm suffered.*"[1273]

117. The cases cited by Defendants were cases bought by private parties sounding in private nuisance,[1274] or other non-nuisance theories,[1275] precisely the sort of cases *Kermit Lumber* found distinguishable and "less than helpful" because they focus on private damages rather than the public interest in abating harm to the public's interest in health and safety.[1276]

118. Defendants' argument that their conduct in the distribution of opioids over the years was distinct and separate so that it could not constitute a continuing injury was explicitly rejected

[1273] 200 W.Va. at 243, 488 S.E.2d at 923 (quotation omitted; emphasis in original).

[1274] *Rhodes v. E.I. du Pont de Nemours & Co.*, 657 F. Supp. 2d 751 (S.D. W. Va. 2009); *Taylor v. Culloden Pub. Serv. Dist.*, 214 W.Va. 639, 591 S.E.2d 197 (2003).

[1275] *Roberts v. W. Virginia Am. Water Co.*, 221 W.Va. 373, 655 S.E.2d 119 (2007) (individual negligence action); *Handley v. Town of Shinnston*, 169 W. Va. 617, 289 S.E.2d 201 (1982) (same); *Graham v. Beverage*, 211 W.Va. 466, 473, n. 13 & 474, 566 S.E.2d 603, 610 n. 13 & 611 (2002) (individual negligence and malicious interference claim).

[1276] Defendants cite only one case that mentions *Kermit Lumber* is *Taylor v. Culloden Pub. Serv. Dist.*, which involved a private, rather than a public, nuisance. 214 W.Va. 639, 591 S.E.2d 197 (2003). *Taylor* illustrates that the analysis for such a private nuisance case differs from that in a public nuisance action. The *Taylor* Court determined that the damage claims in *Taylor* were a continuing tort involving "distinct instances of injury result[ing] from the nuisance , as opposed to a singular injury." *Id.* at 647, 205. From that, the Court concluded that the two-year statute of limitations in subsection 12(a) does not run in a private nuisance action seeking damages for a temporary nuisance "until the date of the last injurious act or when the acts constituting the nuisance have been abated or discontinued." *Id.* at syl. pt. 6. *Taylor* recognized the *Kermit Lumber* rule for an unabated *public nuisance,* that the one-year statute of limitations does not begin to run until the "harm or endangerment to the public health, safety and the environment is abated." *Id.* (quoting *Kermit Lumber*). *Taylor* declined to consider whether plaintiffs should have been permitted to amend their complaint to assert a public nuisance claim, holding "there is no need for Appellants *to seek the benefit*" of the *Kermit Lumber* rule, given its conclusion that the statute of limitations did not present a bar. *Id.* (emphasis added).

by Judge Polster in the MDL.[1277] More importantly, however, Defendants' focus on their conduct as the statute of limitations trigger in a public nuisance action seeking abatement was explicitly rejected in *Kermit Lumber.*[1278] The Court did not even address whether Kermit Lumber's conduct was continuous. Instead, in the very next sentence following the sentence quoted by Defendants concerning the "general rule", the Court rejected that "general rule" as "unworkable in the context of a public nuisance action" where the aim is to correct a condition "which is endangering the 'public health, safety and the environment.'"[1279]

119. This Court has previously rejected Defendants' argument that Plaintiffs are seeking the legal remedy of money damages rather than the equitable remedy of abatement.[1280] Moreover, the Defendants' argument is irrelevant to the *Kermit Lumber* analysis as evidenced by the fact that the State in *Kermit Lumber* was actually seeking "compensatory and punitive damages."[1281] By establishing that public nuisance is both abatable and unabated, Plaintiffs meet *Kermit Lumber's* definition of a temporary and continuing nuisance for which the statute of limitations had not yet began to run.

[1277] *In re: National Prescription Opiate Litigation*, MDL 2804, 2019 WL 4194296 at 13, (N.D. Ohio Sep. 4, 2019) (finding "persuasive" MDL Plaintiffs' response that Defendants' conduct involved "a decades-long marketing and distribution scheme that continues unabated, satisfying the tolling requirement that alleged acts cannot be said to occur on any particular day, but [rather] over a series of days or years" and recognizing that "Courts have allowed the statute of limitations to be tolled when there is a longstanding and demonstrable policy of the forbidden activity." (citations and internal quotations omitted)).

[1278] 200 W.Va. at 245, n. 29; 488 S.E.2d at 925, n.29.

[1279] *Id.* (emphasis added).

[1280] Doc. 1284 at 6-7. The Court reaffirms that ruling for the reasons set forth in Part VII(B)(1), *infra*.

[1281] 488 S.E.2d at 921.

120. In the MDL, Judge Polster came to the same conclusion and held that no statute of limitations applies to an unabated public nuisance under Ohio law.[1282]

121. Interpreting West Virginia law, both Judge Hummel, in Marshall County, and the West Virginia Mass Litigation Panel have applied the holdings in *Kermit Lumber* and found that no statute of limitations applied to public entities' public nuisance abatement claims.[1283] The Supreme Court unanimously denied writs seeking to challenge both of these decisions.[1284] Notably, in *Kermit Lumber,* the Supreme Court was not troubled that the State first learned of the contamination (and Kermit Lumber's actions) in 1987 but did not file its lawsuit until 1995.[1285]

122. Finally, the Court rejects Cardinal's argument raised during trial for the first time,[1286] that Plaintiffs' abatement *remedy* is barred by the statute of limitations. This argument falls on the same grounds as noted previously – whether based on *Dunn v. Rockwell* or *Kermit*

[1282] *In re: National Prescription Opiate Litigation*, 2019 WL 4194296 at 2 ("A well-settled rule in Ohio is that no length of time can legalize a public nuisance and that therefore the statute of limitations does not run against an action to abate such a nuisance.") (quoting 72 Ohio Jur. 3d Nuisances § 22).

[1283] *See Brooke County Commission, et. al. v. Purdue Pharma L.P., et. al.*, Nos. 17-C-248 at *6 (W.Va. Cir. Ct. Marshall County Dec. 28, 2018) (Dkt. 1077-4); *Monongalia County, et al. v. Purdue Pharma L.P.*, et al., Nos. 18-C-222-236 (Dkt. 288.5) (adopting and applying the reasoning and rulings from *Brooke County*).

[1284] *See State ex rel. Cardinal Health v. Hummel,* No. 19-0204 (W.Va. June 4, 2019) (Dkt. 1077.5); *State ex rel. AmerisourceBergen Drug Corp. v. Moats,* No. 19-1051 (W.Va. January 30, 2020) (Dkt. 1077.9). Additionally, in this very case, Special Master Wilkes also denied Defendants' motion to compel Plaintiffs to respond to discovery to identify the date and manner in which Cabell County first learned prescription opioids were being abused or diverted within its geographic boundaries. Doc. 248, Discovery Ruling 1 at *2-3. In doing so, he found that "West Virginia law provides the statute of limitations on nuisance actions does not begin to run until the nuisance is abated." *Id.* (citing *Kermit Lumber, supra*); *see also id.* at *2-3 ("[W]hat Cabell County has disclosed is satisfactory, in light of the fact that *as a matter of law* the statute of limitations doesn't begin to run until the nuisance is abated." *Id.* (emphasis added)).

[1285] 200 W.Va. at 225-226; 488 S.E.2d at 905-06.

[1286] Doc. 1453 at 75.

Lumber – there simply is no running statute of limitations on an equitable claim to abate an unabated nuisance.

123. In an attempt to avoid *Kermit Lumber*, Cardinal attempts to reframe the nuisance – arguing that the nuisance is their act of distributing pills.[1287] The premise of this argument – that the focus should be on conduct not condition -- is also refuted below. With respect to any statute of limitations argument under *Kermit Lumber,* it is undisputed that here, "the harm or endangerment to the public health, safety and the environment is [un]abated," such that the statute of limitations remains tolled. [1288]

124. This Court finds that the harms created by the public nuisance caused by the Defendants remain unabated, therefore, the Court concludes that the statute of limitations in this equitable action to abate a public nuisance has not yet begun to run regardless of whether *Dunn* or *Kermit Lumber* governs.

VII. Remedy

A. Adoption of the Abatement Plan.

125. The West Virginia Supreme Court of Appeals long has held that an injunction to abate a public nuisance may take the form of either a restraining injunction to prevent a prospective nuisance or, far more commonly, an affirmative injunction to effectuate remediation of an existing or continuing nuisance.[1289]

[1287] *Id.* at 76.

[1288] 200 W.Va. at 245-246; 488 S.E.2d at 925-926.

[1289] *See Duff v. Morgantown Energy Assocs.*, 187 W. Va. 712, 716, 421 S.E.2d 253, 257 (1992) ("courts generally grant injunctions to abate existing nuisances"); *see also Kermit Lumber*, 200 W.Va. at 245, 488 S.E.2d at 925 ("A public nuisance action usually seeks to have some harm which affects the public health and safety abated. Thus, until such harm is abated, the public nuisance is continuing . . .."); *Weston v. Ralston*, 48 W. Va. 170, 194, 36 S.E. 446, 456 (1900)

126. The prospective costs for addiction treatment and services Plaintiffs seek are akin to the environmental cleanup costs sought and found recoverable to abate the public nuisance in *Kermit Lumber*.[1290] This is what the State Court Mass Litigation Panel has held in opioid litigation.[1291]

127. This Court previously recognized that it has the equitable power under West Virginia law to order the funding of an abatement plan "as the functional equivalent of an injunction" when an injunction requiring the Defendants to abate the nuisance is not feasible.[1292]

128. The Plaintiffs seek an award solely for the implementation of the Abatement Plan. The Court previously rejected Defendants' argument that abatement funding would always be impermissible under West Virginia Law.[1293] The Court agrees with Plaintiffs that under West Virginia Law it has the authority to fund a remediation plan as a form of abatement.

129. Plaintiffs provided sufficient evidence they have an infrastructure and institutional capacity to carry out its proposed abatement plan.

("Courts of equity interfere to restrain and prevent public nuisances threatened or in progress, as well as to abate those already existing.") (internal quotation marks and citation omitted).

[1290] 200 W.Va. at 245; 488 S.E.2d at 925.

[1291] *See In re Opioid Litig.*, Civil Action No. 19-C-9000 (W. Va. Cir. Ct. of Kanawha Cty. July 29, 2020) (Order re Plaintiffs' Motion to Strike Defendants' Notices of Non-Party Fault) (Doc. No. 813-1 at 9) ("[T]he cost of providing opioid education programs or treatment centers might be part of the equitable relief to abate Plaintiffs' alleged public nuisance – the opioid crisis . . .").

[1292] Doc. 1285 at 6-7; *see also In re Nat'l Prescr. Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4043938, at *2 (N.D. Ohio Aug. 26, 2019) ("If Defendants are eventually found liable for creating the opioid crisis, there is no realistic way the Court could order . . . that . . . Defendants abate the crisis themselves (Defendants do not have the requisite infrastructure) . . .").

[1293] Doc 1285 at 7.

130. Other courts have confirmed that abatement is appropriate where, as here, the plaintiff has demonstrated that the interference with public rights "is so unreasonable that it must be stopped."[1294]

131. Relevant West Virginia law requires Plaintiffs to establish entitlement to abatement to a "reasonable certainty" or "beyond all ground of fair questioning."[1295] This Court concludes that Plaintiffs have met that burden here, and the appropriate remedy in this case is an order requiring the Defendants to fund an abatement plan.

132. As set forth above, the Plaintiffs' experts Dr. Alexander, Dr. Waller and Dr. Keyes testified there are evidence-based solutions that can be put in place that have been proven to help abate the Opioid Epidemic.[1296] Those solutions have been detailed in the Abatement Plan of Dr. Alexander.[1297]

133. The testimony of the Plaintiffs' experts supports a finding that the Abatement Plan will abate the nuisance, save substantial numbers of lives in Cabell County and the City of Huntington, save substantial numbers of people from becoming addicted to opioids in the future,

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[1294] Second Restatement § 821B cmt. i ("In an action for injunction [abatement], the question is whether the activity itself is so unreasonable that it must be stopped. It may be reasonable to continue an important activity if payment is made for the harm it is causing, but unreasonable to continue without paying."); *see also Sullivan v. Chief Justice for Admin. & Mgmt. of the Trial Ct.*, 858 N.E.2d 699, 715 (Mass. 2006) (same) (quoting Restatement).

[1295] *Duff v. Morgantown Energy Ass'n*, 187 W. Va. 712, 421 S.E.2d 253, 258 n.9 (1992) ("The plaintiff seeking the injunction to abate the prospective nuisance bears the burden of proving that the proposed conduct will constitute a nuisance beyond all ground of fair questioning. There is no dispute among the parties in this case that older West Virginia cases follow the standard that an activity will be enjoined prospectively if it is reasonably certain that such activity will constitute a nuisance."); *see also City of Huntington v. AmerisourceBergen Drug Corp.*, 2021 WL 1235025, at *3 (S.D. W. Va. March 31, 2021) (quoting *Duff*, first sentence).

[1296] FOF, ¶ 606-608, 616.

[1297] FOF, ¶ 606-608.

and eliminate the negative impact this nuisance has had on Cabell County and the City of Huntington.[1298]

134. The Court finds it reasonably certain that Plaintiffs' Abatement Plan set forth above is necessary to abate the public nuisance and orders the funding of the full fifteen-year plan.

135. The Court finds it appropriate and necessary to award the full fifteen-year cost of the plan so that the plan may be efficiently and cost-effectively administered; however, the Court concludes that it is appropriate to consider the time value of money and award $1,802,428,070 as the present value of the future costs of the program.[1299]

136. Therefore, the Court directs the Plaintiffs to establish a trust to receive and conserve the funds awarded in this action and limit expenditure of the funds, after payment of attorney fees and litigation expenses, to the implementation of the Redress Model of Dr. Alexander's Abatement Plan. The Plaintiffs are directed to provide to the Court its proposed governance structure for approval by this Court. It is the Court's intention that the trust will be governed by trustees who are approved and supervised by the Court. The governing documents of the trust will be subject to Court approval and the operation of the trust will be subject to court-supervision.[1300]

[1298] FOF, ¶ 614.

[1299] FOF, ¶ 657.

[1300] Defendants contend that if the abatement fund disburses money to any State controlled entity, it would result in a double windfall for the state as a result of the Defendants' settlements with the Defendants. Doc. 1485 at 14-15. This Court has previously rejected Defendants' attempts to bar Plaintiffs' claims based on those settlements with the State. Doc. 1291. The now Court bases its rulings on the following: Defendants cannot establish that the Plaintiffs and the WVAG were in privity with each other; the doctrine of virtual representation is inapplicable; Plaintiffs' claims for abatement of a public nuisance by a city and a county are not the same claims as the damages claims previously raised by the State and the WVAG; and Plaintiffs' claims were not released by the WVAG because the plain language of the releases release only the claims of the State and the WVAG, the only claims the State and the WVAG had the power to bring or release. *See also* Doc. 242. In any event, selection of entities to implement the Abatement Plan is premature prior to the creation of the fund and its governing structure.

B. Defendants' Challenges to the Abatement Plan have no Merit.

137. Defendants have raised a number of objections to the Abatement Plan. The Court concludes that none of these objections bar the abatement relief ordered by the Court herein. For the reasons set forth below, the objections are overruled.

1. Plaintiffs' Abatement Plan Sounds in Equity and Cannot be Characterized as Damages.

138. The Court, sitting in equity, finds and concludes that the appropriate remedy to address the opioid crisis in Cabell and Huntington is the abatement of the nuisance by implementing the Plaintiffs' Abatement Plan.

139. The Court rejects Defendants' argument that Plaintiffs' Abatement Plan constitutes damages and is therefore an improper equitable remedy.[1301] Plaintiffs' Abatement Plan is limited to rectifying the going forward harms resulting from the opioid epidemic, that is, the conditions that constitute the public nuisance Defendants' have caused. As such, it meets the applicable test for an equitable abatement plan as a remedy for a public nuisance.

140. Defendants correctly cite the applicable legal principle: "Unlike damages, which are intended to "compensate the harmed party for harms already caused by the nuisance," the *"abatement remedy is intended to compensate the plaintiff for the costs of rectifying the nuisance, going forward.*"[1302]

141. Here, every element of Plaintiffs' Abatement Plan meets Defendants' test in that they all constitute "compensat[ion to] the plaintiff[s] for the costs of rectifying the nuisance, going

[1301] Doc. 1451 at 8-13; Doc. 1453 at 49-56.

[1302] Doc. 1451at p.13 (quoting *In re Natl. Prescription Opiate Litig.*, 2019 WL 4043938, at *1 (N.D. Ohio August 26, 2019) (emphasis added).

forward."[1303] Defendants identify no element of the abatement plan that is not linked to rectifying the opioid epidemic public nuisance, nor do they offer any plan to redress the serious, ongoing epidemic in Cabell and Huntington.

142. Like the abatement fund ordered in *People v. ConAgra Grocery Products Co.,*[1304] the remedy here clearly constitutes abatement:

> Here, plaintiff sought the equitable remedy of abatement for the nuisance because the hazard created by defendants was continuing to cause harm to children, and that harm could be prevented only by removing the hazard. Plaintiff did not seek to recover for any prior accrued harm nor did it seek compensation of any kind. The deposits that the trial court required defendants to make into the abatement account would be utilized not to recompense anyone for accrued harm but solely to pay for the prospective removal of the hazards defendants had created.[1305]

The opioid epidemic here is a hazard created by Defendants; it continues to cause harm; and the Abatement Plan is designed to remove the hazard that is causing the harms. Plaintiffs do not seek to recover for any prior accrued harms, nor compensation of any kind for future harms, such as lost revenue or property values. Unlike a damage award where the Plaintiffs are free to expend the recovery any way they choose, an equitable fund for abatement of the opioid epidemic can only be utilized to pay for the prospective elimination of the epidemic.

143. Defendants argue that no West Virginia Court has required the funding of an abatement plan to reduce the effects of a public nuisance. The West Virginia Mass Litigation Panel ("MLP"), however, characterized similar claims as equitable in the state court opioid litigation.[1306] As Judge Polster noted, these same Defendants' arguments "appear to confuse the

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[1303] *Id.* at p.13.

[1304] 17 Cal. App. 5th 51, 227 Cal. Rptr. 3d 499 (2017)

[1305] 17 Cal. App. 5th at 133, 227 Cal. Rptr. 3d at 569.

[1306] *See In re Opioid Litig.*, No. 19-C-9000 (W. Va. Cir. Ct., Kanawha Cty. July 29, 2020) at 5, ¶¶ 5-6 ("[T]he Panel concludes that the Apportionment Statutes (both the 2005 Act and the 2015 Act)

forward-looking, equitable remedy of abatement and the rearward-looking remedy of damages."[1307] Other Courts addressing opioid epidemic abatement claims have ruled similarly,[1308] as have other courts hearing public nuisance cases sounding in equity.[1309]

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do not apply to Plaintiffs' equitable claims of public nuisance . . .. The statutes apply only to claims for damages and do not refer to abatement or other equitable relief."); *id.* at 9, ¶¶ 13-14 ("Damages, whether future or past, are focused on compensation for an injury or loss to make the injured party whole. Abatement is to rectify the nuisance itself. . . . The Court concludes and holds that [nuisance abatement] costs are in the nature of equitable relief, not past damages."),

The Supreme Court of Appeals of West Virginia addressed the MLP's orders in a writ proceeding. *State ex rel. AmerisourceBergen Drug Corp. v. Moats*, No. 20-0694, 2021 WL 2390204, at *8 (W. Va. June 11, 2021). The Court specifically noted that "other courts have recognized that an injunction may entail the payment of money by a defendant." *Id.* at *7. Many of the plaintiffs in *ABDC, supra,* however, had pending claims for damages. Therefore, the Court granted the writ to the extent that the Panel's orders required legal claims to be tried after the bench trial. *Id.* at *10. Notably, the Court upheld the equitable nature of the State's public nuisance claim and did not grant the writ with respect to the State. *Id.* at * 8, n.55. Like the Plaintiffs here, the State in *ABDC* had waived and was not seeking damages in its public nuisance. *Id.* at *4 (noting State's argument that 2015 Non-Party Fault Act did not apply to State's claims seeking abatement of public nuisance).

[1307] *In re Nat'l Prescription Opiate Litig.,* No. 1:17-MD-2804, 2019 WL 4043938, at *1.

[1308] *SER Mike Hunter v. Purdue Pharma L.P., et al.,* Case No. CJ-2017-816 (Aug. 26, 2019) at awarding abatement remedy that included addiction treatment); *State of Washington v. McKesson,* No. 19-2-06975-9 SEA (King County, Wash July 6, 2021) (holding in opioid case where Dr. Alexander is expert witness proposing similar abatement plan that "Abatement is an equitable remedy, even when the relief sought in abatement is monetary." (citing *ConAgra, supra*)).

[1309] *ConAgra*, 17 Cal. App. 5th at 132 ("The abatement funds was not a 'thinly disguised' damages award. The distinction between an abatement order and a damages award is stark. . . . An equitable remedy's sole purpose is to eliminate the hazard that is causing prospective harm to the plaintiff."); *In re Lead Paint Litig.*, 924 A.2d 484, 499 (N.J. 2007) ("[T]he public entity, as the modern representative of the sovereign in public nuisance litigation, has only the right to abate. Although, historically that has included the right to visit upon the owner of the land from which the public nuisance emanates, the obligations, *including the costs*, of the abatement, there is no right . . . for the public entity to seek to collect money damages in general." (internal citations omitted) (emphasis added).

144. Cardinal separately argues, as a matter of federal law, that any money awarded must be incidental to a prohibitory injunction.[1310] While abatement often takes the form of an injunction, that is because an injunction requiring the defendant to undertake such remediation is feasible; here, however, "defendants 'do not have the requisite infrastructure,'" and, thus "it is unclear why the court could not order funding as the functional equivalent."[1311] Judge Polster summarized the rationale behind the abatement fund requested by Plaintiffs:

> If Defendants are eventually found liable for creating the opioid crisis, there is no realistic way the Court could order either that: (1) Defendants abate the crisis themselves (Defendants do not have the requisite infrastructure), or (2) Plaintiffs abate the crisis and then order Defendants to pay Plaintiffs the costs incurred in doing so (Plaintiffs do not have the financial resources). Thus, the Court must, if Defendants are found liable, have some mechanism to predict and fairly award prospective future costs to abate the crisis.[1312]

On the other hand, the Court has found that Plaintiffs have the infrastructure to implement a court supervised abatement plan,[1313] and the Abatement Plan includes the provision for "Surveillance, Evaluation, and Leadership."[1314]

[1310] Defendants argue that, for this proposition, federal law sets forth this Court's equitable jurisdiction. Doc. No. 1451 at 14. Caselaw on this issue rarely makes the distinction between state and federal equity jurisprudence – with courts at both levels looking back to England for guidance. As such, the Court concludes that the cited state decisions are persuasive authority.

[1311] Doc. 1285 at p.6 (footnotes omitted) (quoting *In re Nat'l Prescription Opiate Litig.,* 2019 WL 4043938, at *2). Here, Defendants have not argued that they have the requisite infrastructure, and the Court has expressly found as a matter of fact that Defendants do not. FOF, ¶ 606.

[1312] *In re Nat'l Prescription Opiate Litig.,* 2019 WL 4043938, at *2.

[1313] FOF, ¶¶ 614(j).

[1314] Mr. Barrett calculated that this intervention (category 1F "Surveillance, Evaluation, and Leadership") will cost $5.2 million over the 15-year duration of the Abatement Plan. 6/29 Trial Tr. (Barrett) at 107, 110. The subcategory includes costs for an executive director, data analysts, and a staff assistant. Id. at 132-33. Dr. Alexander explained the importance of this category of the Abatement Plan:

> [S]urveillance, evaluation, and leadership is important because there has to be a mission control to this plan. Surveillance and evaluation allow for iterative

145. The Court concludes that the abatement fund sought by Plaintiffs is consistent with both the purposes behind abatement and the broad equitable power of the Court.[1315]

146. Finally, Cardinal argues that there are no examples of a federal court ordering the creation of an equitable fund pursuant to its equitable powers. To the contrary, courts across the country have found that a federal court order creating a court-supervised fund, most commonly in the context of medical monitoring cases, is a proper exercise of equitable jurisdiction rather than a claim for damages. The Court in *Day v. NLO*, *Inc.*, explained the distinction:

> [A] court may also establish an elaborate medical monitoring program of its own, managed by court-appointed court-supervised trustees, pursuant to which a plaintiff is monitored by particular physicians and the medical data produced is utilized for group studies. In this situation, a defendant, of course, would finance the program as well as being required by the Court to address issues as they develop during the program administration. *Under these circumstances, the relief constitutes injunctive relief . . ..*[1316]

> refinement and fine-tuning of the plan over time as the epidemic continues to evolve.

6/28 Trial Tr. (Alexander) at 136-37.

[1315] Moreover, nuisances are not limited to conduct and *conditions* that interfere with a public right also constitute a public nuisance, *see infra,* Part VII(B)(3), thus, the requirement that prohibitory injunction issue where conduct has already stopped but condition caused by the continues would render it impossible to abate the harms caused by the conduct. No case law supports this extreme result.

[1316] 144 F.R.D. 330, 335-36 (S.D. Ohio 1992) (emphasis added); *see also In re NLO, Inc.*, 5 F.3d 154, 159 (6th Cir. 1993) (denying writ in *Day*) (cases relied upon by the district court "generally support the proposition that such relief is injunctive in nature").

There are many other examples.[1317] These holdings are not limited to medical monitoring cases.[1318]

147. Cardinal's response is that the court supervision contemplated by these cases means that "the Court (itself or through trustees or monitors) would have to decide (i) which programs should be funded (ii) in what amounts (iii) for how long and (iv) with what requirements for reporting and accountability."[1319] With respect to the first three, the Court is already largely

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[1317] *Yslava v. Hughes Aircraft Co.*, 845 F. Supp. 705, 713 (D. Ariz. 1993) ("Here, plaintiffs do not merely seek money from Hughes. Plaintiffs seek to implement a court-supervised program requiring ongoing, elaborate medical monitoring. Accordingly, plaintiffs' relief qualifies as injunctive relief. . .."); *Cook v. Rockwell Int'l Corp.*, 778 F. Supp. 512, 515 (D. Colo. 1991) ("Rockwell argues that dismissal is appropriate because a medical monitoring claim is not cognizable as "injunctive relief." I conclude that dismissal of this claim is not appropriate."); *Barth v. Firestone Tire & Rubber Co.*, 661 F. Supp. 193, 204 (N.D. Cal. 1987) (finding equitable claim for establishment and maintenance of a monitoring program which will pool and share knowledge about the results of the alleged exposure and will provide for diagnosis and preventive medical advice); *Donovan v. Philip Morris USA, Inc.*, 268 F.R.D. 1, 23 (D. Mass. 2010); *In re Copley Pharm., Inc.*, 161 F.R.D. 456, 469 (D. Wyo. 1995) ("During the course of the trial, the Court will also consider evidence relevant to the Plaintiffs' request for the equitable remedy of medical monitoring. . . [B]ecause of the equitable nature of medical monitoring, this issue should not be submitted to the jury."). There are also many examples of state courts so holding. *See, e.g., Ayers v. Jackson Township,* 106 N.J. 557, 525 A.2d 287, 314 (1987) ("[T]he use of a court-supervised fund to administer medical-surveillance payments in mass exposure cases ... is a highly appropriate exercise of the Court's equitable powers."); *Burns v. Jaquays Min. Corp.,* 156 Ariz. 375, 752 P.2d 28, 34 (App.Ct.1987) (holding that court-supervised medical surveillance fund is exercise of court's equitable powers).

[1318] *Corvello v. New England Gas Co.*, 532 F. Supp. 2d 396, 398–99 (D.R.I. 2008) (refusing to dismiss claim for injunctive relief where plaintiffs brought public nuisance claims seeking compensatory damages and an injunction requiring defendant to "pay money into a fund sufficient to clean and remediate the contamination"); *United States v. Price*, 688 F.2d 204, 212 (3d Cir. 1982) ("A request for funds for a diagnostic study of the public health threat posed by the continuing contamination and its abatement is not, in any sense, a traditional form of damages."). Cardinal tries to limit *Price* to relief available under federal statutes, *see* Doc. 1453-1 at 54-56, while asserting that there is a general rule against equitable relief in the form of payment of money. *Id.* (citing *Jaffee v. U.S.*, 592 F.2d 712, 715 (3d Cir. 1979). *Jaffee*, however, involved claims not by a government plaintiff seeking to abate a public nuisance, but private plaintiffs seeking to defray their costs for future personal *injury* treatment, which the court held is "a traditional form of damages in tort compensation for medical expenses to be incurred in the future." 592 F.2d 715.

[1319] Doc. 1487 at 27.

undertaking that analysis as part of this trial. Details regarding implementation of the Abatement Plan (including reporting) can be addressed in subsequent proceedings as the infrastructure of the fund is developed and submitted to the Court for approval.[1320]

148. The Abatement Plan here seeks *the abatement of the public nuisance (the opioid epidemic), not compensation for past harms.* The structure of the Abatement Plan falls squarely within the cases cited above. Plaintiffs seek a Court-supervised fund to implement the Abatement Plan. The Abatement Plan is remedial and specifically directed at abating the opioid epidemic (rather than compensating for past or projected injuries). Unlike a damage award which can be used for any purpose, the use of the proposed fund is restricted to implementing the Abatement Plan. Simply put, *the remedy falls within equity – it is not "a repackaged claim for damages."*[1321]

2. Plaintiffs' Abatement Claims are Not Barred by the "Adequate Remedy at Law" Doctrine.

149. Cardinal claims that Plaintiffs have an adequate remedy at law that, as a matter of federal jurisdictional law, bars their abatement claim in equity.[1322] Cardinal's argument relies on inapposite case law involving claims by private parties. The standard is applied differently in the context of governmental actions – especially ones like this involving public health and safety. Moreover, the "legal remedies" argued by Cardinal to be adequate are insufficient to constitute an adequate remedy at law.

[1320] *Cf. Perrine v. E.I. du Pont de Nemours & Co.,* 225 W. Va. 482, 505, 694 S.E.2d 815, 838 (2010) (in implementing medical monitoring program, circuit court entered five orders pertaining to post-judgment matters following evidentiary hearing which resolved issues concerning the scope, duration and cost of medical monitoring plan).

[1321] *Rederford v. U.S. Airways, Inc.*, 589 F.3d 30, 37 (1st Cir. 2009).

[1322] *See* Doc. 1453 at 40-49.

150. As the Fourth Circuit has made clear in *Env't Def. Fund, Inc. v. Lamphier*, claims for equitable relief by governmental plaintiffs are held to a different standard than claims brought by private parties.[1323] This is particularly true "[w]here the plaintiff is a sovereign and where the activity may endanger the public health." In such cases, the emphasis shifts from traditional equitable concerns "to concern for the general public interest."[1324] Thus, a governmental plaintiff is "not bound to conform with the requirements of private litigation," such as "show[ing] irreparable injury and that it [lacks] an adequate remedy at law," when it acts to effectuate statutory policies; instead, the requirement is only that the relief be "in the public interest."[1325] And, *Lamphier* specifically held that "this rationale applies equally to *state enforcement of federal and state health laws*."[1326]

151. Thus, under *Lamphier,* all that is required is a showing that the Abatement Plan is "in the public interest," without regard to whether there is any purportedly adequate legal remedy. Here, there is no reasonable argument that the abatement plan is not in the public interest and Defendants do not contend otherwise.

[1323] 714 F.2d 331, 337 (4th Cir. 1983) ("the law of injunctions differs with respect to governmental plaintiffs (or private attorneys general) as opposed to private individuals").

[1324] *Id.* at 337-38 (quoting *Shafer v. United States,* 229 F.2d 124, 128 (4th Cir.1956)).

[1325] *Id.* at 338 (quoting *Shafer, supra*); *see also United States v. Shelton Wholesale, Inc.,* 34 F. Supp. 2d 1147, 1166–67 (W.D. Mo. 1999) ("When the Government seeks an injunction pursuant to statute to protect the public health, the requirements applicable to private litigants in equity do not apply. The Government need not show irreparable harm, or inadequate remedy at law." (citations omitted)), *aff'd,* 277 F.3d 998 (8th Cir. 2002); *United States v. Articles of Drug,* 633 F. Supp. 316, 326 (D. Neb. 1986) ("[T]he government is not bound to prove the absence of an adequate remedy at law where a statute authorizes an injunction."), *aff'd in part, rev'd in part on other grounds,* 825 F.2d 1238 (8th Cir. 1987).

[1326] *Id.* (emphasis added).

152. Cardinal's out-of-circuit precedent does not change this analysis. Cardinal relies heavily on *Sonner v. Premier Nutrition Corp.*,[1327] an outlier decision of the Ninth Circuit. While Cardinal suggests that the Fourth Circuit agrees,[1328] the agreement by our circuit noted by the *Sonner* Court was with the proposition that "state law cannot circumscribe a federal court's equitable powers even when state law affords the rule of decision."[1329] Plaintiffs are not seeking to circumscribe a federal court's equitable powers to what state law allows; rather, Plaintiffs seek equitable relief allowed by state law.

153. *Sonner,* which involved a private class action, does not cite or address *Lamphier*'s holdings regarding the requirements for an equitable relief sought by a governmental entity. Similarly, the district courts applying *Sonner* to dismiss claims for equitable relief highlighted by Cardinal all involve claims by private entities, and all the cited decisions were from California district courts in the Ninth Circuit.[1330] *Lamphier,* as a decision of the Fourth Circuit, is binding here and mandates rejection of Cardinal's claim.[1331]

[1327] 971 F.3d 834 (9th Cir. 2020).

[1328] Doc. 1446-1 at 43 (citing *Sonner*, 971 F.3d at 843 (citing *SSMC, Inc. v. N.V. Steffen*, 102 F.3d 704, 708 (4th Cir. 1996)).

[1329] *SSMC*, 102 F.3d at 708 (quoting *Guaranty Trust Co. v. York*, 326 U.S. 99, 106 (1945).

[1330] *See* Doc. 1446-1 at 43 n.139.

[1331] Cardinal argues that *Lamphier* is limited to cases where the government seeking action is sovereign. Doc. 1487 at 21. Notably, *Lamphier's* holding expressly applied to the private parties acting as "private attorney generals." 714 F.2d at 337–38. While the Plaintiffs here are political subdivision and not sovereigns, they are acting under the authority of state statutes authorizing abatement. W.Va. Code § 8-12-5 (13), (23), (44); W.Va. Code § 7-1-3kk. Cardinal offers no explanation why *Lamphier's* holding should apply to private parties and not actual governmental entities such as Plaintiffs. Second, *Lamphier's* rule that traditional equitable requirement are inapplicable in governmental actions to protect the public health has second basis – statutory authorization. 714 F.2d at 338. Like the statutes in *Lamphier,* Plaintiffs are effectuating the policy of W.Va. Code § 8-12-5 (13), (23), (44) and W.Va. Code § 7-1-3kk which expressly authorize abatement actions, and the only requirement is that the government act out of "concern for the general public interest." *Lamphier, supra.*

154. In any event, the request for abatement here satisfies the requirement that legal remedies be inadequate. The long-established standard for determining whether a remedy at law is adequate is as follows: "Before equitable relief is foreclosed, the legal remedy must be as complete, practical, and efficient as the equitable remedy available."[1332] Thus, even if *Sonner's* analysis governs, the damage claims identified by Cardinal do not constitute adequate remedies at law.

155. Here, Plaintiffs are bringing an equitable public nuisance claim where the remedy sought is abatement of the public nuisance. This claim vindicates the government's interest in securing public rights – such as protection against interference with "the public health, the public safety, the public peace, the public comfort or the public convenience."[1333] When a public agency has authority to represent a political subdivision in bringing the public nuisance claim, the body can, as here, maintain a proceeding to enjoin or abate a public nuisance.[1334] The second type of claim is a claim for damages. As Judge Polster explains, the two claims are fundamentally different:

> In a traditional public nuisance case, a municipal entity who is harmed by the maintenance of a nuisance will give notice to and ask the offending party to abate the nuisance. If the offending party is unable or unwilling to abate, the harmed party can, when appropriate, abate the nuisance themselves or ask the court

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[1332] Dobbs, Law of Remedies (3d ed.) § 2.5 & n.201(1) (citing *Terrace v. Thompson,* 263 U.S. 197, 214, 44 S. Ct. 15, 17, 68 L. Ed. 255 (1923) ("the legal remedy must be as complete, practical and efficient as that which equity could afford"); *see also* 30A C.J.S. Equity § 23 (The existence of a remedy at law does not deprive equity of jurisdiction unless that remedy is clear, full, adequate, and complete. . . . Thus, equity will assume jurisdiction if one's remedy at law is not as complete as, or would be more difficult than, the remedy in equity, or is less effective, or is less complete or satisfactory.") (footnotes omitted)); *Stolt-Nielsen, S.A. v. United States,* 442 F.3d 177, 187 (3d Cir. 2006), *as amended* (May 16, 2006) (same).

[1333] Second Restatement, § 821B(2)(A).

[1334] *Id.* at § 821C(2)(B); *id* at cmt c ("A public official who is authorized to represent the state or an appropriate subdivision in an action to abate or enjoin a public nuisance may of course maintain the action.").

> for the right to do so, and then seek compensation for the costs of abating the nuisance. This compensation is equitable in nature. The goal is not to compensate the harmed party for harms already caused by the nuisance. This would be an award of damages. Instead, an abatement remedy is intended to compensate the plaintiff for the costs of rectifying the nuisance, going forward.[1335]

156. The Court concludes that the fact that Plaintiffs once sought damages (and even if such claims remained) does not change the nature of the abatement remedy. The Abatement Plan sought by Plaintiffs is forward looking and does not seek recovery of any past expenditures. Instead, Plaintiffs seek an abatement order calling for the creation of a trust fund that will "rectify the nuisance going forward."

157. Finally, Cardinal focuses on the Abatement Plan expenditures for substance abuse treatment and equates them to the recovery of future medical expenses in a tort action. Courts, in the context of resolving medical monitoring claims, have long distinguished the recovery by individuals for future medical expenses from the creation of an equitable fund for purposes of determining whether a legal remedy was adequate. For example, the Court in *Barth v. Firestone Tire & Rubber Co.,* concluded that "no remedy at law exists that would permit a court to fashion an underlying remedy such as the medical monitoring fund sought here" where plaintiffs sought the establishment and maintenance of a monitoring program which will pool and share knowledge about the results of the alleged exposure and will provide for diagnosis and preventive medical advice.[1336] The court noted that "plaintiffs still may seek other forms of remedy at law, but the monitoring program sought here is not a remedy available at law."[1337]

[1335] *In re Nat'l Prescription Opiate Litig.*, 2019 WL 4043938, at *1.

[1336] 661 F. Supp. 193, 205 (N.D. Cal. 1987).

[1337] *Id.; see also O'Connor v. Boeing N. Am., Inc.*, 184 F.R.D. 311, 337–38 (C.D. Cal. 1998) ("Recovering the *cost* of future medical monitoring on an individual basis, however, will not provide Plaintiffs with the relief they seek, as Plaintiffs' program is designed not only to detect

158. The Court finds that the Abatement Plan here is analogous to these medical monitoring funds. As noted above, the Abatement Plan seeks the creation of a Court-supervised fund that does more than pay for treatment for individuals. The Plan creates the necessary treatment infrastructure, expands the treatment workforce, and connects individuals to care (including programs to decrease relapse and increase retention in treatment). And unlike a claim for damages, the money in trust fund Plaintiffs seek is restricted to implementing the Abatement Plan to abate the opioid epidemic.

159. Simply paying for the cost to respond to more people who are overdosing, or more infants born withdrawing is clearly an inadequate remedy for this epidemic. First, a damage award cannot be limited to implementing the Abatement Plan.[1338] Damage awards are especially inadequate for a governmental entity seeking to prevent harm to its residents. As in *Barth v. Firestone Tire & Rubber Co., supra,* as no remedy at law exists that would permit a court to fashion an underlying remedy like the Abatement Plan as part of a damage award, damage claims at law are not adequate remedies. Thus, any damage claim is inadequate to abate the opioid epidemic and is not a remedy that is "complete, practical, and efficient" substitute for the Plaintiffs' claims seeking implementation of the entire Abatement Plan through the establishment of a Court-supervised fund.

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signs of latent disease, but also to *share information* regarding the identification and development of latent diseases among class members." (emphasis in original)).

[1338] *Cf. Bower v. Westinghouse Elec. Corp.*, 206 W. Va. 133, 143, 522 S.E.2d 424, 434 (1999) (noting the distinction between medical monitoring granted through the establishment of a court-administered fund and lump-sum damage awards).

3. The Remedy of Abatement Extends to the Elimination of the Opioid Epidemic and is Not Limited to Eliminating Defendants' Contributing Conduct.

160. Defendants argue that the remedy of abatement is limited to an injunction stopping conduct.[1339] This argument premised on the incorrect notion that a nuisance may only be defined based upon conduct.[1340] The Court concludes that this premise is incorrect as a matter of law, as West Virginia common law has long recognized that a *condition* that substantially interferes with public rights constitutes a public nuisance. Moreover, case law establishes the right of a public entity to seek, as abatement, the remediation of the conditions caused by the nuisance as abatement.

161. West Virginian decisions consistently hold that *conditions* that interfere with a public right constitute a public nuisance. In 1955, the Supreme Court of Appeals held in *Martin v. Williams* that "[a] condition is a nuisance when it clearly appears that enjoyment of property is materially lessened, and physical comfort of persons in their homes is materially interfered with thereby."[1341] Modern decisions have recognized *Martin's* holding.[1342] And, other cases make it clear that either an act *or* condition can constitute a nuisance.[1343]

162. Defendants improperly conflate what is necessary to establish *liability* for a public nuisance with the resulting condition which – after liability is proven – is the proper focus for the

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[1339] Doc. 1441-1 at 9.

[1340] Doc. 1441-1 at 9.

[1341] 141 W.Va. 595, 610–611, 93 S.E.2d 835, 844 (1956) (citations omitted).

[1342] *Burch v. Nedpower Mount Storm, LLC,* 220 W. Va. 443, 450–51, 647 S.E.2d 879, 886–87 (2007); *Hendricks v. Stalnaker*, 181 W. Va. 31, 33, 380 S.E.2d 198, 200 (1989).

[1343] *Hark v. Mountain Fork Lumber Co.,* 127 W. Va. 586, 595, 34 S.E.2d 348, 354 (1945) ("A public nuisance is an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons."); *Hendricks*, 181 W. Va. at 31, 380 S.E.2d at 200 ("This definition of nuisance includes acts or conditions that affect either the general public or a limited number of persons."); *Sharon Steel Corp.*, 175 W. Va. at 483, 334 S.E.2d at 620–21 (quoting *Hark*).

remedy of abatement. While Defendants' conduct is unquestionably a necessary element in determining their liability in a public nuisance abatement action,[1344] it does not follow that the remedy of abatement is limited solely to stopping the conduct when harms to public health and safety would otherwise remain. Thus, the Court concludes that abatement is not limited to eliminating defendants' wrongful conduct.

163. Courts have "broad equitable authority to abate [a] nuisance."[1345] This is hornbook law.[1346] Indeed, the Supreme Court of Appeals held in *CashCall, Inc. v. Morrisey*, that courts "have broad powers to fashion equitable relief," and "a court's equitable powers assume an even broader, more flexible character when the public interest is involved."[1347] The *CashCall* Court quoted the U.S. Supreme Court's caution on limiting equitable jurisdiction:

> Unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied.[1348]

The Court rejects Defendants' limitation of the broad remedy of abatement to an injunction halting their conduct as clearly contrary to these equitable principles.

[1344] COL, Part IV.

[1345] *Ypsilanti Charter Twp. v. Kircher*, 281 Mich. App. 251, 275–76, 761 N.W.2d 761, 777 (2008); *see also Thanos v. D.C.,* 109 A.3d 1084, 1093–94 (D.C. 2014) ("the broad authority to fashion equitable relief for the purposes of enjoining, abating, and preventing the continuation or recurrence of [the] nuisance"); *Northfield Twp. v. Kircher*, No. 212260, 2000 WL 33409146, at *1 (Mich. Ct. App. Aug. 11, 2000) ("Trial courts have broad discretion in fashioning appropriate remedies to abate public nuisances." (citations and internal quotations omitted)).

[1346] 58 Am. Jur. 2d Nuisances § 288 ("An action to abate a public nuisance is one of an equitable nature. Equity has always had the authority to abate a public nuisance. The purpose of giving equity jurisdiction in public nuisance actions is to offer remedies more complete than those available at law.").

[1347] No. 12-1274, 2014 WL 2404300, at *19 (Mem.) (W. Va. May 30, 2014).

[1348] *Id.* (quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 66 S.Ct. 1086 (1946)).

164. The Defendants concede that in environmental cases, "[t]he object of a public nuisance action is to abate or stop the harm to the public health, safety, and the environment," where abatement consists of removing the remaining pollution from the environment.[1349] For this proposition, Defendants rely on *Kermit Lumber*, where the defendant's arsenic pollution migrated offsite, threating the health and safety of the public. Tellingly, the *Kermit Lumber* Court did not limit the State's abatement to stopping Defendants' operations, a remedy that would have been meaningless as the defendant there had ceased operations at the site.[1350] Instead, as Defendants acknowledge, the State sought remediation and cleanup of the arsenic.[1351] And, while the State also sought damages in *Kermit Lumber,* it sought damages in addition to abatement.[1352]

165. Defendants argue that the *Kermit Lumber* Court did not extend abatement to medical treatment – a remedy that was not requested by the State in *Kermit Lumber*. Even if the absence of express approval of a remedy not sought has any precedential value, the nuisance here – the opioid epidemic – is materially different from the environmental contamination in *Kermit Lumber*. Treatment of addiction is necessary here because addiction itself results in many other of the conditions that constitute interference with public rights: crime, communicable diseases, destruction of neighborhoods, burdens on social systems, etc. Defendants' interpretation of *Kermit Lumber* also is simply inconsistent with that Court's focus on the importance of abating the continuing harms of the unabated nuisance.[1353]

[1349] Doc. 1451 at p.12 (quoting *Kermit Lumber, supra*).

[1350] *Kermit Lumber*, 200 W. Va. at 226, n. 4, 488 S.E.2d at 906, n. 4.

[1351] Doc. 1451 at p.12, n.22.

[1352] *Id.*

[1353] *See Kermit Lumber*, *supra*.

166. Finally, Defendants contend that funding treatment and other elements of the Abatement Plan, which will be performed by entities other the Plaintiffs, is improper. This Court has already rejected this argument.[1354] Funding treatment by third-parties here would be the same as funding remediation of environment contamination by third party remediation experts.

167. Thus, an "abatement order is an equitable remedy," and its "sole purpose is to eliminate the hazard that is causing prospective harm to the plaintiff."[1355] Here, the Abatement Plan proposes to alleviate the opioid epidemic which is the hazard causing the prospective harms identified above.

4. Because Defendants Are Responsible for the Abatement of the Opioid Epidemic in Cabell and Huntington, the Scope of the Abatement Plan is both Necessary and Appropriate.

168. In addition to their structural challenge to the requested Court-supervised fund to implement the Abatement Plan, Defendants challenge the scope of the Abatement Plan. The Court rejects these challenges. The premise for these arguments – that Defendants' liability is for something other than abatement of the opioid epidemic in Cabell and Huntington – is false, and the remedies set forth in the Abatement Plan are all designed to accomplish that goal.

[1354] Doc. 1285 at 6-7 ("If the facts prove that an injunction requiring remediation would not be feasible, it is unclear why the court could not order funding as the functional equivalent.").

[1355] *ConAgra*, 17 Cal. App. 5th at 132, 227 Cal. Rptr. 3d at 569.

a. Because Defendants are Jointly and Severally Liable for the Opioid Epidemic in Cabell and Huntington, the Abatement Plan is Appropriately Directed at Abating the Entire Epidemic.

169. First, the Court concludes that Defendants are jointly and severally liable to abate the opioid epidemic harms in Cabell and Huntington. West Virginia's common law rule is that joint tortfeasors presumptively are jointly and severally liable to satisfy a judgment.[1356] Long ago, the Supreme Court of Appeals recognized that defendants who were concurrently liable in creating a nuisance were subject to joint liability.[1357] Moreover, joint liability for abatement of a public nuisance is subject to a different and more liberal standard in equity.[1358]

170. While recently, the West Virginia Legislature has limited the application of the common law rule of joint and several liability,[1359] those enactments apply only to causes of action seeking damages.[1360] The current 2015 Act does not apply to Plaintiffs' public nuisance claim seeking only equitable abatement relief. This Court recognized the inapplicability of these statutes

[1356] *Sitzes v. Anchor Motor Freight, Inc.*, 169 W. Va. 698, 289 S.E.2d 679, 684 (1982).

[1357] *Baker v. City of Wheeling*, 117 W. Va. 362, 185 S.E. 842, 844 (1936).

[1358] *McMechen v. Hitchman-Glendale Consol. Coal Co.*, 88 W. Va. 633, 107 S.E. 480, 482 (1921) ("Although brought into existence or maintained by the separate acts of a number of persons, a nuisance, considered in all of its aspects and elements, may be an entire thing. Limited in its functions to a mere matter of compensation for damages, a court of law could not, under all circumstances, treat it as an entirety, but a court of equity can do so, because of its more extensive remedial powers.").

[1359] *See* W. Va. Code § 55-7-13c(a) (2015) ("2015 Act"); *see also* W. Va. Code § 55-7-24 (2005) (repealed 2015).

[1360] W. Va. Code § 55-7-13c(a).

in granting Plaintiffs' motion to strike Defendants' notices of non-party fault served pursuant to the 2015 Act.[1361] Thus, common law joint and several liability applies in this case.[1362]

171. Since joint and several liability applies, and Plaintiffs have established that Defendants are "*a* factor in causing some aspect of [their] harm,"[1363] the Plaintiffs have made a "*prima facie* showing," and Defendants then have the burden of showing the harm "is capable of

[1361] *See* Order issued March 31, 2021 (ECF No. 1247) at 1 ("Plaintiffs' Motion to Strike Defendants' Notices of Non-Party Fault (ECF No. 224) is Granted"); *see also* Doc. No. 1083-3, *writ* denied, *State ex rel. AmerisourceBergen Drug Corp. v. Hon. Alan D. Moats*, ___ W. Va. ___, 859 S.E.2d 374, 378-79 (W. Va. June 11, 2021) ("We conclude that the Panel did not clearly err when it found that the 2015 amendments do not apply to the public nuisance claims."). As Justice Hutchinson recognized, this Court's order is consistent with the long-standing maxim that "[s]tatutes in derogation of the common law are strictly construed." *Id.* at *19 (Hutchinson, J., concurring) (quoting yl. pt. 1, *Kellar v. James*, 63 W.Va. 139, 59 S.E. 939 (1907) and citing syl. pt. 3, *Bank of Weston v. Thomas*, 75 W.Va. 321, 83 S.E. 985 (1914); syl. pt. 5, *Phillips v. Larry's Drive-In Pharmacy, Inc.*, 220 W. Va. 484, 647 S.E.2d 920 (2007).

[1362] *See,* Doc. No. 1083-3. During trial Defendants argued that "'[t]wo or more tort-feasors acting independently, without concert, collusion, or pursuit of a common design, in the perpetration of like wrongful acts at the same time, working like injury to the same subject, are not jointly liable for injury subsequently resulting to any person from combination of the consequences of such wrongful acts by the operation of natural causes.'" Doc. 1485 at 20 (quoting syl. pt. 1, *Farley v. Crystal Coal & Coke Co.*, 85 W. Va. 595, 595, 102 S.E. 265, 265 (1920)). *Farley* was an action for damages, and the subsequent decision in *McMechen,* cited *Farley as the reason to a different and more liberal standard in equity applies.* 107 S.E. at 482. Similarly, *West*, 168 W. Va. at 589, 285 S.E.2d at 678, the Court found independent contractor liability in the case of a nuisance. *Id.* at syl. pt. 2. As such the Court did not have occasion to address the availability of injunctive relief under *McMechen.* Finally, this doctrine is inconsistent with modern caselaw imposing liability to

[1363] COL, ¶¶ 72-73.

apportionment."[1364] Thus, Defendants bear the burden of demonstrating that both the Plaintiffs' harm and the applicable remedy are divisible.[1365]

172. A public nuisance by its nature is a condition that typically is indivisible and for which liability cannot be apportioned. The West Virginia Supreme Court of Appeals recognized over a century ago that, "[a]lthough brought into existence or maintained by the separate acts of a number of persons, a nuisance, considered in all of its aspects and elements, may be an entire thing."[1366] This is especially so where, as here, a court is determining the application of an equitable remedy such as abatement.[1367] Defendants therefore must demonstrate that the nuisance harms caused by each potentially responsible party are clearly separable, or else their liability is joint and several.

173. Thus, the Court concludes that Defendants' arguments that Plaintiffs' abatement plan should be rejected because it is not tied to Defendants' conduct fail on this basis. Similarly, the claims that the Abatement Plan is not tailored to the wrong in this case because the Abatement Plan treats addicts who did not first become addicted as a result of Defendants' conduct also

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[1364] *Blankenship v. General Motors Corp.*, 185 W. Va. 350, 406 S.E.2d 781, 786 (1991) (emphasis in original); *see also Johnson by Johnson v. General Motors Corp.*, 190 W. Va. 236, 438 S.E.2d 28, 34 (1993) ("'If the alleged defect is proven by Plaintiffs by a preponderance of the evidence to have been a factor in causing Plaintiffs' injuries, then the manufacturer can limit its liability by showing that Plaintiffs' injuries are capable of apportionment between the initial collision and any injury enhanced by the alleged defect.'") (quoting jury instruction).

[1365] *See*, *e.g.*, *Johnson*, 190 W. Va. 236, 438 S.E.2d at 33 ("However, if the jury is unable to apportion the damages, then the injury is indivisible and . . . the tortfeasors will then be jointly and severally liable."); *Grant Thornton, LLP v. FDIC*, 694 F. Supp. 2d 506, 525 (S.D. W. Va. 2010) (Faber, J.) ("'Unless sufficient evidence permits the factfinder to determine that damages are divisible, they are indivisible.'") (quoting Restatement (Third) of Torts § 26, cmt. g), *rev'd on other grounds*, 435 Fed. Appx. 188 (4th Cir. June 17, 2011).

[1366] *McMechen*, 88 W. Va. 633, 107 S.E. at 482.

[1367] *See id.* ("Limited in its functions to a mere matter of compensation for damages, a court of law could not, under all circumstances, treat [the nuisance] as an entirety, but a court of equity can do so, because of its more extensive remedial powers.").

fail.[1368] Defendants complain that Plaintiffs have left the Court to speculate regarding what portions of the Abatement Plan is related to Defendants' unreasonable conduct.[1369] However, the burden is on Defendants to show that the loss can be allocated and to show a reasonable basis for the allocation. Defendants have not provided any basis for doing so.

174. The Court has already concluded that Defendants are a proximate cause of the opioid epidemic in Cabell and Huntington[1370] and that it is reasonably certain that all of the elements of the Abatement Plan are necessary to abate the harms of the Opioid Epidemic.[1371] The only argument Defendants make for apportionment was a single sentence in the final page of their final brief: "At a minimum, the harms flowing from prescription opioid abuse, on the one hand, and the use of illicit non-prescription opioids, on the other hand, are plainly distinct injuries that cannot be viewed as arising from "one" nuisance for purposes of tort law." Factually, this argument is inconsistent with the Court's findings regarding causation of the opioid epidemic harm of illegal heroin and fentanyl use.[1372] More importantly here, Defendants have not presented any reasoned argument for *how* to apportion liability between these supposedly "distinct" injuries. While Defendants correctly point out that "'the magnitude of each indivisible component part' of a Plaintiffs' harm 'cannot be determined with precision' does not mean that the injury is not

[1368] *See* Doc. 1451 at 14-15. This argument also fails because the existence of the opioid epidemic proximately caused by Defendants is a contagion in the community that is a cause of new addictions -- regardless of whether the new addicts became addicted to pills or other opioids. Trial Tr. June 28, 2021 (Alexander) ("My plan is to abate the opioid epidemic in the community and I don't think that that can be done without – I think there's one epidemic, not two; an opioid epidemic, not a prescription epidemic and a fentanyl and heroin epidemic.").

[1369] Doc. 1453 at 68-69.

[1370] COL, ¶¶ 86, *et sec.*

[1371] COL, ¶ 134.

[1372] FOF, Part VII(A)(3)(c); COL, ¶¶ 103, 105.

susceptible to apportionment, because only a 'reasonable basis' is required,"[1373] Defendants have not supplied a record or argument that would permit the Court do any more than guess. An allocation based on guess is not a reasonable basis.[1374]

175. Here, Defendants do not contest that they bear the burden of showing that (i) the harms caused by the public nuisance are divisible and can clearly or reasonably be apportioned and (ii) that a reasonable basis for apportionment exists. Consequently, Defendants are jointly and severally responsible for the abatement of the opioid epidemic in Cabell County.

b. <u>The Abatement Plan will not Result in a Windfall.</u>

176. The Court also rejects Defendants claim that the Abatement Plan will result in a windfall. As an initial matter, a windfall to Plaintiffs would be an impossibility. As noted above the Abatement Plan ordered herein is a court supervised trust under the continuing jurisdiction of the Court where the trust documents and this order establishing the fund would limit expenditures to implementing elimination of the opioid epidemic in Cabell and Huntington as set forth in the Abatement Plan. Because neither Cabell nor Huntington would receive the funds, there could never be a windfall. Moreover, as the Court has found, the Abatement Plan itself is conservative.[1375]

177. Defendants claim that the Abatement Plan fails to consider the amount of unmet need. Similarly, Defendants argue that that the majority of the programs under the Abatement

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[1373] Doc. 1485 at 17 (quoting *Grant Thornton, LLP v. FDIC*, 694 F. Supp. 2d 506, 525 (S.D. W. Va. 2010) (Faber, J.), *reversed on other grounds,* 435 F. App'x 188, 525 (4th Cir. 2011)).

[1374] Notably, in *Grant Thornton,* the losses were financial, required apportionment between only two parties, involved distinct periods of time, and Court had the benefit of a damage expert on the issue on allocation. *See* 694 F. Supp. 2d at 522.

[1375] FOF, ¶ 621.

Plan have not traditionally been provided by Plaintiffs and that the Plaintiffs do not intend to provide those programs and services. None of these considerations will lead to a windfall.

178. With respect to current funding, the Court has found that current funding is unstable,[1376] and that stability is necessary for epidemic response efforts to be effective.[1377] Moreover, current funding is clearly insufficient to implement the Abatement Plan and abate the opioid epidemic. [1378]

179. In addition to there being no guarantee, the current funding, largely consisting of grants, which are generally considered a collateral source.[1379] The same is true for Medicare, Medicaid, and private insurance.[1380] While Defendants contest the applicability of the collateral source rule to this action in equity, the Court concludes that Defendants should not receive a windfall by letting private insurers, taxpayers, and those private entities who fund grants continue to bear the burden of attempting to fund the remediation of the opioid epidemic which Defendants caused.[1381] And, as noted above, there can be no windfall to the Plaintiffs here because the use of the funds will be limited to the Abatement Plan. The issue here is not whether Plaintiffs can recover for expenses paid by third parties, the issue is who should bear the burden of abating the ongoing

[1376] FOF, ¶ 614(d).

[1377] FOF, ¶ 614(f).

[1378] FOF, ¶ 614(a).

[1379] *Kenney v. Liston*, 233 W. Va. 620, 632, 760 S.E.2d 434, 446 (2014) (services rendered gratuitously or paid for by another are collateral sources).

[1380] *Kenney,* 760 S.E.2d at 629-630, fn. 41, fn. 42 (Medicare, Medicaid, and private insurance are collateral sources under West Virginia law). Of course, none of Defendants' "windfall" analysis considers subrogation claims by these payors.

[1381] The Court made a pretrial ruling conditionally admitting the evidence of these third-party payments. The Court reserved ruling on the question of whether "the collateral source rule does or does not apply as a substantive rule of damages in this case." Doc. 1281-0, p. 7, n. 3.

nuisance. Under these circumstances, the equities counsel against allowing Defendants to receive a windfall.

c. The Abatement Plan does Not Require Defendants to Remediate the Wrongs of Others.

180. Cardinal challenges a number of remedies in the Abatement Plan as improperly requiring remediation based on the wrongs of others.[1382] But it does not address whether these alleged wrongs are foreseeably related to the harms it caused. Cardinal does not deny that these supposed wrongs of others are part and parcel of the opioid epidemic – indeed, with respect to physicians and medical boards, Defendants made them the focus of their defense.[1383] Consequently, the Court concludes that Cardinal's liability for these elements is a consequence of joint liability and concurrent causation and, as such, the Defendants cannot escape their responsibility on this basis.[1384]

181. The Court concludes that the challenge to certain categories of the Abatement Plan as remote fairs no better. Defendants do not even attempt to argue that the need for any of these programs was not foreseeable –the touchstone for determining legal cause.[1385] Nor could they. For example, the Court concludes that it is foreseeable that if you generate a need for substance abuse treatment, additional medical professionals need to be trained to provide those services.

182. Finally, the Court concludes that many of the rest of the challenged programs are directed at consequences of the opioid epidemic that must be addressed if the epidemic is to be

[1382] Doc. 1453 at 56-64.

[1383] Doc. 1453 at 23.

[1384] *See* COL, Part V(B).

[1385] Doc. 1469 at 47-50.

abated. School children in households with families with opioid use disorder, drug checking services, harm reduction services such as needle exchanges, and testing for HIV and HCV all fall into this category.[1386] The Court concludes that these are all necessary elements of the plan to abate the opioid epidemic in Cabell and Huntington.

d. Plaintiffs' Expert Testimony Establishes Their Entitlement to Future OUD Treatment Costs.

183. Defendants argue that Dr. Alexander's abatement plan overstates treatment need because another Plaintiff's expert, Dr. Waller who testified that "the one-year success rate for OUD treatment is approximately 84%"[1387] Defendants' misstate the testimony of Dr. Waller and Dr. Alexander.[1388]

[1386] Cardinal tries to distort Professor Alexander's recognition of the epidemic-relatedness of these public health harms and their treatment services by stating that "Cardinal is not responsible for 'the history of trauma' faced by 'women who are commercial sex workers' or the stresses of adolescence." Doc. 1453 at 67 (quoting 6/28/21 Trial Tr. (Alexander) at 62.). Professor Alexander's testimony was describing an existing Cabell and Huntington court program he examined when developing his Redress Model. *See* 6/28/21 Trial Tr. (Alexander) at 33-34 ("[T]he WEAR program is a separate tract within the Drug Court for women who are commercial sex workers and who have a history of trauma."). Professor Alexander's Redress Model does not single out commercial sex workers for unique services but *does* recognize that many pregnant women and new mothers with OUD have likewise experienced significant traumas, including sexual assault and domestic violence.

[1387] FOF, ¶ 630.

[1388] FOF, ¶¶ 630-34.

184. Even if Defendants' argument had a legitimate factual premise, it legally misses the point. As a result of the epidemic, people will become addicted to and overdose on opioids. There will be new cases that are required to be abated, whether or not they are the direct result of Defendants' conduct. They will be a part of the opioid epidemic. Defendants will remain a proximate cause of the epidemic. In addition, trial evidence establishes that the existence of the opioid epidemic independently causes new addicts.[1389] Finally, to the extent Defendants cannot be relieved of liability for this part of the opioid epidemic in Cabell and Huntington, because, as noted above, they failed to meet their burden to convince the Court what portion of this harm is proper to allocate elsewhere.[1390]

* * * *

185. The Court enters final judgment for the Plaintiffs and against Defendants AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation as set forth herein. Defendants' responsibility to fund the Abatement Plan is joint and several.

186. To the extent any argument or objection set forth by Defendants in any motion, filing or pleading, is not specifically addressed by the Court's Findings of Fact and Conclusions of Law, such argument and/or objection made by Defendants is hereby denied and overruled.

187. The Court retains jurisdiction over the parties to supervise the implementation of the Abatement Plan.

188. The Court will enter such further orders pertaining to the implementation of the Abatement Plan in due course as necessary.

It is so ORDERED.

[1389] Trial Tr. 6/28 (Alexander) at 152 (Dr. Alexander explained that you can have people who newly develop OUD in the future for all sorts of reasons and who join the population, and you could also have people who drop out of the population); *Id.* at 154 (Recognizing that "there is one

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opioid epidemic…there's a lot of dynamic of different directions that people may develop harms and experience harms and, you know, move towards recovery and then backslide, but it's one opioid epidemic. And so, my plan addresses that.").

[1390] *See* COL, Part VII(B)(4)(i). The cases cited by Defendants are inapposite, as the experts failed to segregate conduct for which Defendants were liable from conduct for which *no one* was culpable. *See, e.g., Hagale Indus., Inc. v. Land's End, Inc.*, No. 00-3474-CV-S-4, 2002 WL 34365830, at *5 (W.D. Mo. Dec. 2, 2002) ("Mr. Roberts' and most of Mr. Stickley's calculations are inadmissible because they failed to classify which costs were incurred because of Lands' End's alleged conduct and which costs were unavoidable."). Here, because Defendants are a proximate cause of the epidemic, they are responsible for the entire epidemic because they have not met their burden to separate and allocate parts of the harm to others).

CERTIFICATE OF SERVICE

I certify that on August 26, 2021, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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